

(12) **United States Patent**
Chiu et al.

(10) **Patent No.:** **US 11,027,061 B2**
(45) **Date of Patent:** **Jun. 8, 2021**

(54) **FLEXIBLE CANNULA INSERTION DEVICE, SYSTEM AND PROCESS**

(71) Applicant: **Medtronic MiniMed, Inc.**, Northridge, CA (US)

(72) Inventors: **Chia-Hung Chiu**, Pasadena, CA (US);
Hsifu Wang, Northridge, CA (US);
Rebecca K. Gottlieb, Culver City, CA (US)

(73) Assignee: **Medtronic MiniMed, Inc.**, Northridge, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 405 days.

(21) Appl. No.: **15/973,471**

(22) Filed: **May 7, 2018**

(65) **Prior Publication Data**

US 2018/0318550 A1 Nov. 8, 2018

Related U.S. Application Data

(60) Provisional application No. 62/503,274, filed on May 8, 2017.

(51) **Int. Cl.**
A61M 25/00 (2006.01)
A61M 39/02 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61M 5/158** (2013.01); **A61L 29/041** (2013.01); **A61L 29/06** (2013.01); **A61M 5/142** (2013.01); **A61M 5/14248** (2013.01); **A61M 25/0009** (2013.01); **A61M 25/0043** (2013.01); **A61M 39/02** (2013.01); **A61M 39/08** (2013.01); **A61B 17/3415** (2013.01); **A61B 2017/3454** (2013.01);
(Continued)

(58) **Field of Classification Search**

CPC A61M 5/14248; A61M 5/158; A61M 2005/14252; A61M 2005/1585; A61M 2005/1587; A61M 25/0043; A61M 25/0045; A61M 25/145; A61M 39/02; A61B 17/3415
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,755,173 A * 7/1988 Konopka A61M 25/0606 128/DIG. 26
5,071,408 A 12/1991 Ahmed et al.
(Continued)

OTHER PUBLICATIONS

International Preliminary Report on Patentability dated Nov. 21, 2019, from application No. PCT/US2018/031455.
(Continued)

Primary Examiner — Nathan R Price

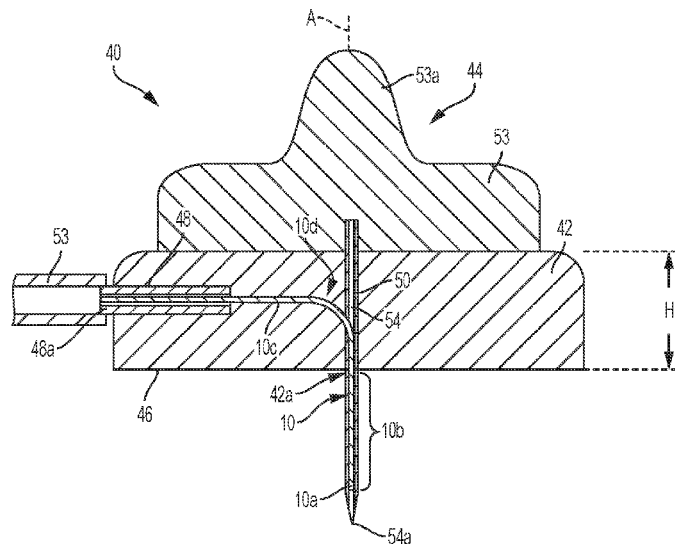
Assistant Examiner — Tasnim Mehjabin Ahmed

(74) *Attorney, Agent, or Firm* — Foley & Lardner LLP

(57) **ABSTRACT**

An insertion set system includes a base configured to be secured to a patient, and a flexible tubing on the base. The flexible tubing has a distal end portion forming a cannula to be inserted into the patient. An inserter having a needle is received by the base. The needle has a channel in which the distal end portion of the flexible tubing is received. The needle is able to slide relative to the flexible tubing, to selectively withdraw the needle off of the distal end portion of the flexible tubing. The base may include a passage for fluid flow arranged transverse to the axial dimension of the distal end portion of the flexible tubing.

24 Claims, 11 Drawing Sheets



(51)	Int. Cl.		6,949,084 B2 *	9/2005	Marggi	A61M 25/0097
	<i>A61M 5/158</i>	(2006.01)				604/174
	<i>A61L 29/06</i>	(2006.01)	8,721,656 B2	5/2014	De Juan et al.	
	<i>A61M 5/142</i>	(2006.01)	9,381,112 B1	7/2016	Sponsell et al.	
	<i>A61M 39/08</i>	(2006.01)	2009/0048563 A1 *	2/2009	Ethelfeld	A61M 5/158
	<i>A61L 29/04</i>	(2006.01)				604/174
	<i>A61M 25/06</i>	(2006.01)	2009/0076451 A1	3/2009	Teisen-Simony et al.	
	<i>A61B 17/34</i>	(2006.01)	2015/0217102 A1	8/2015	Bourgeois et al.	
			2016/0074217 A1	3/2016	Price et al.	
			2019/0117256 A1	4/2019	Jager	

(52) **U.S. Cl.**
 CPC ... *A61M 25/065* (2013.01); *A61M 2005/1585*
 (2013.01); *A61M 2005/1587* (2013.01); *A61M*
2025/0059 (2013.01)

OTHER PUBLICATIONS

Non-Final Office Action dated Apr. 6, 2020, from U.S. Appl. No. 15/973,465.
 International Search Report and Written Opinion dated Oct. 24, 2018, from application No. PCT/US2018/031455.
 Final Office Action dated Jul. 13, 2020, from U.S. Appl. No. 15/973,465.
 Non-Final Office Action dated Oct. 29, 2020, from U.S. Appl. No. 15/973,465.
 Notice of Allowance dated Feb. 23, 2021, from U.S. Appl. No. 15/973,465.

(56) **References Cited**
 U.S. PATENT DOCUMENTS

5,370,607	A	12/1994	Memmen	
5,380,290	A	1/1995	Makower et al.	
5,568,806	A	10/1996	Cheney et al.	
5,586,553	A	12/1996	Halili et al.	
5,951,521	A *	9/1999	Mastrototaro	A61B 5/14865
				604/174
5,954,643	A	9/1999	Vanantwerp et al.	

* cited by examiner

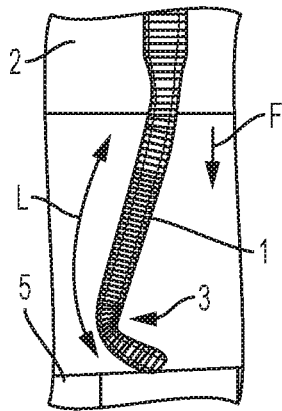


FIG. 1
PRIOR ART

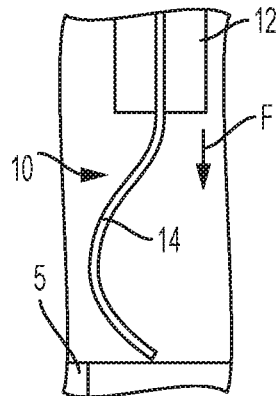


FIG. 4

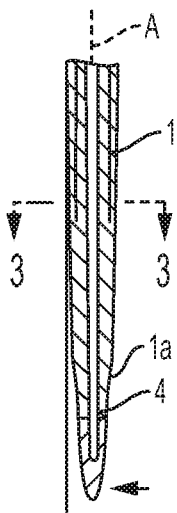


FIG. 2
PRIOR ART

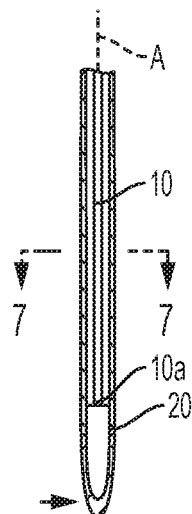


FIG. 6

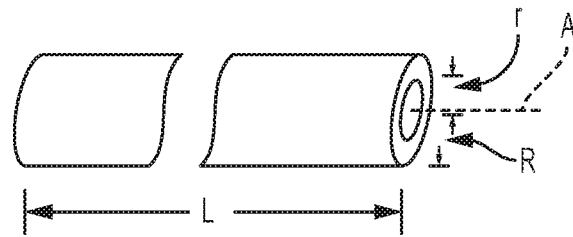


FIG. 5

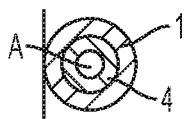


FIG. 3
PRIOR ART



FIG. 7



FIG. 8

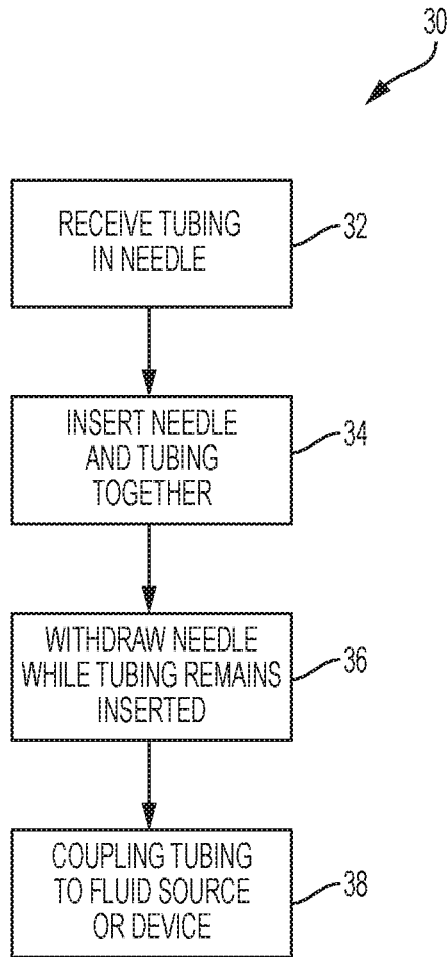


FIG. 9

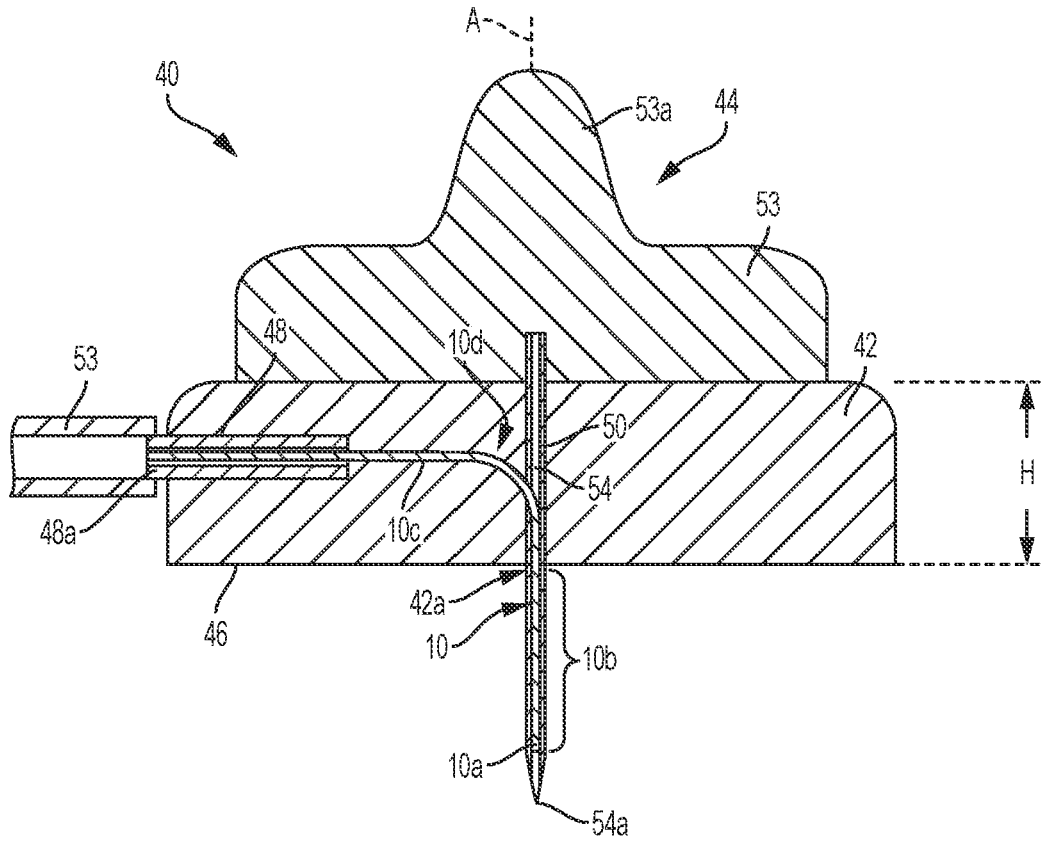


FIG. 10

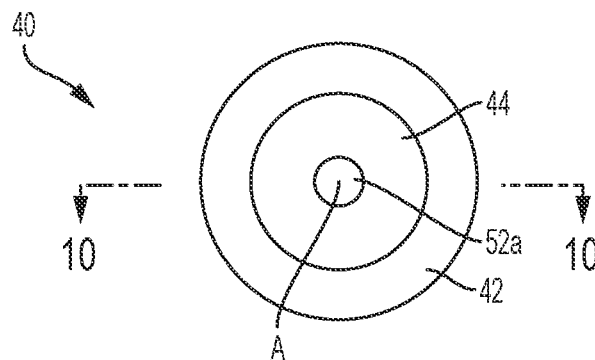


FIG. 11

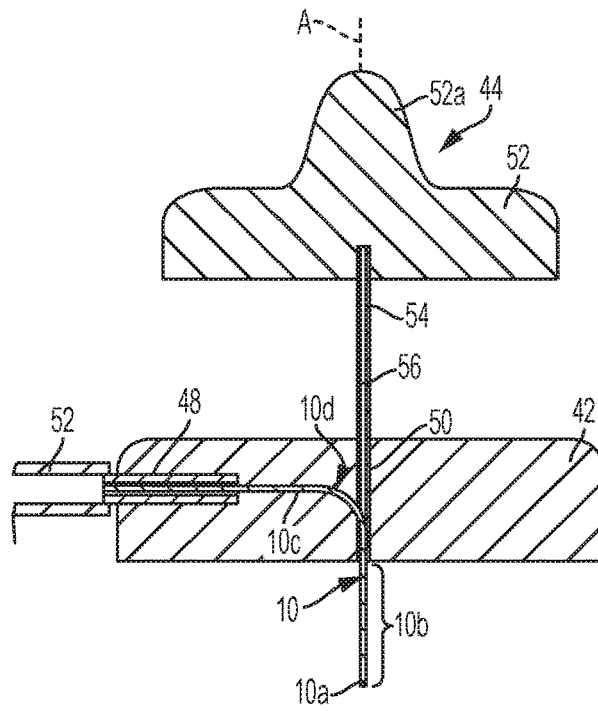


FIG. 12

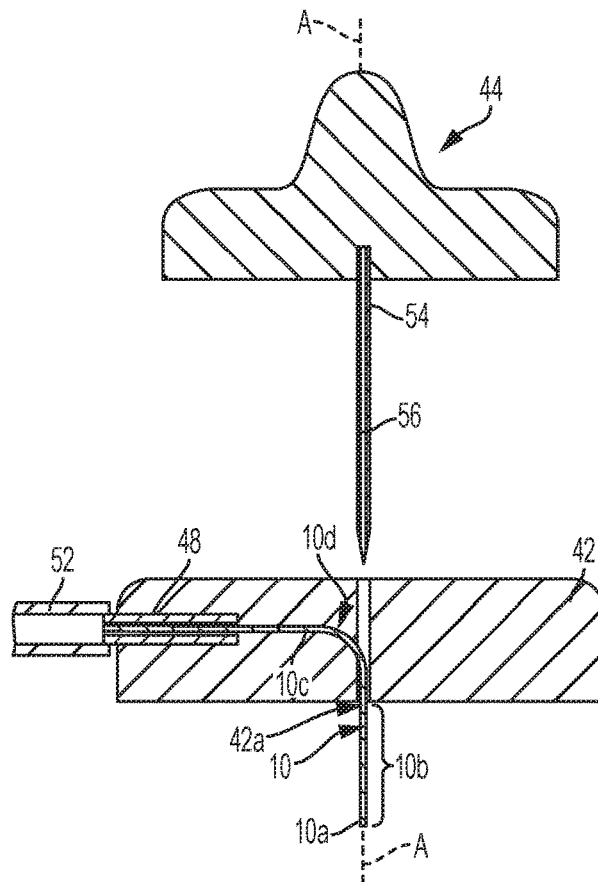


FIG. 13

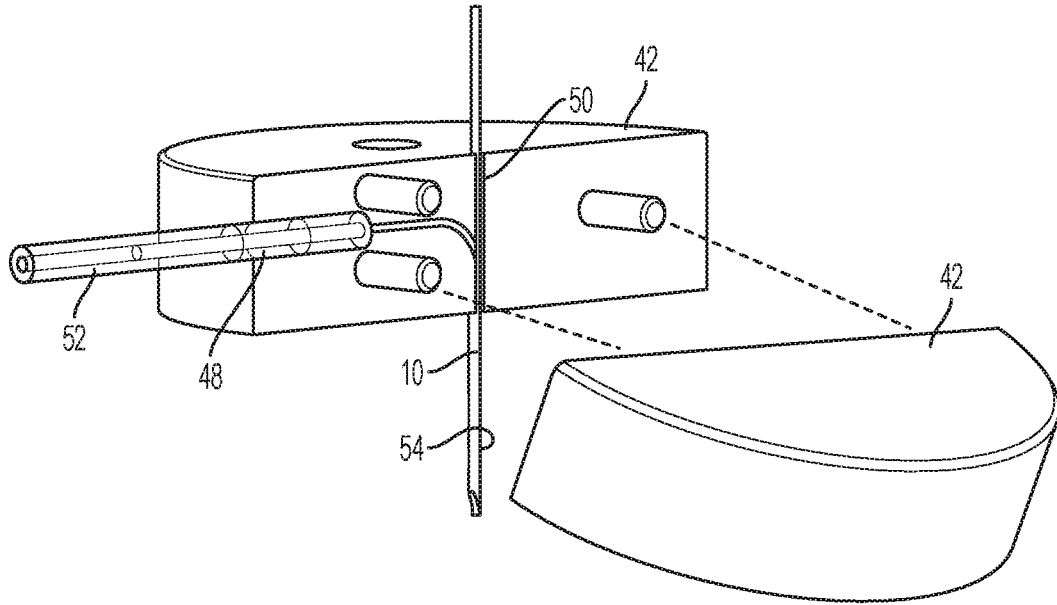


FIG. 14

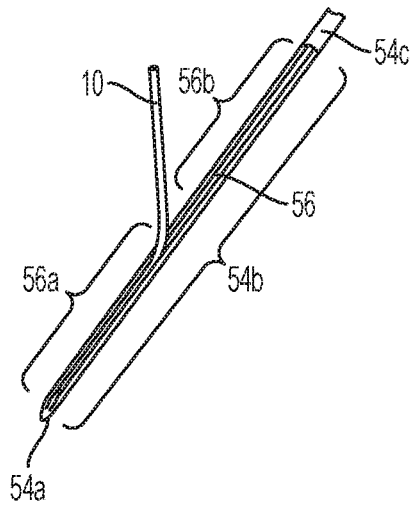


FIG. 15

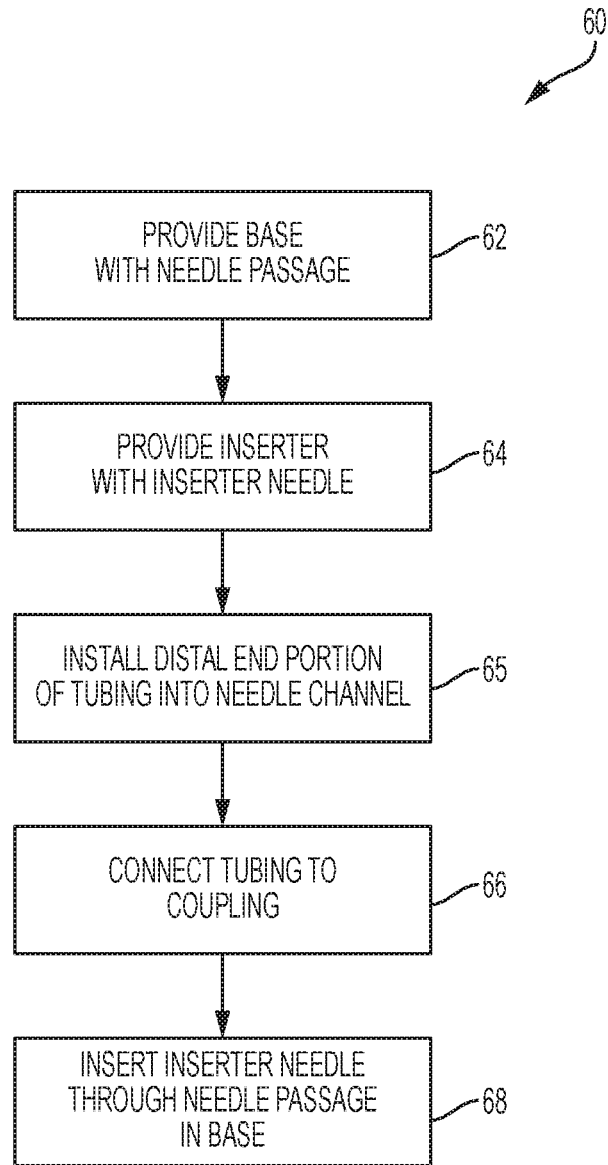


FIG. 16

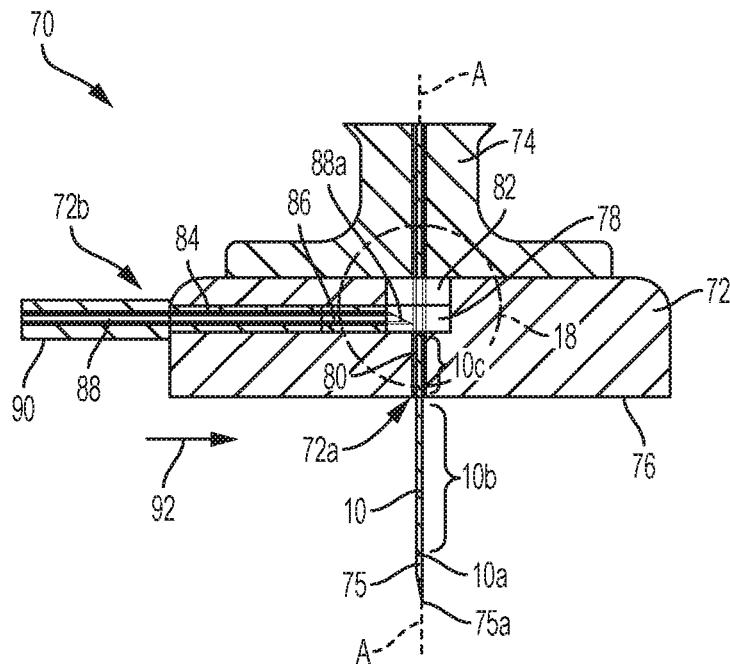


FIG. 17

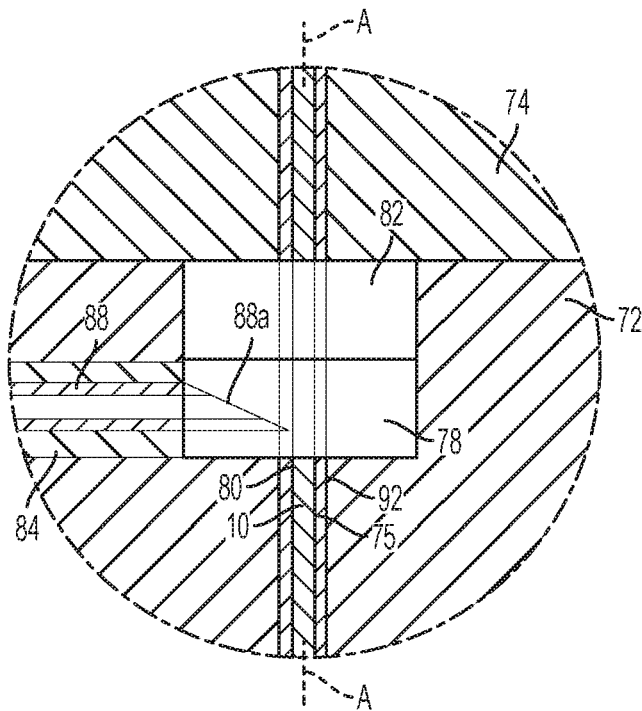


FIG. 18

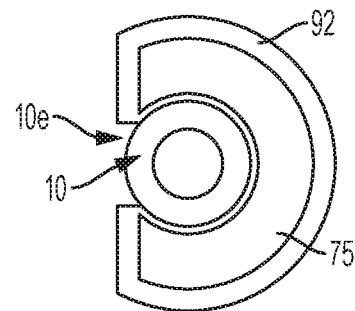


FIG. 19

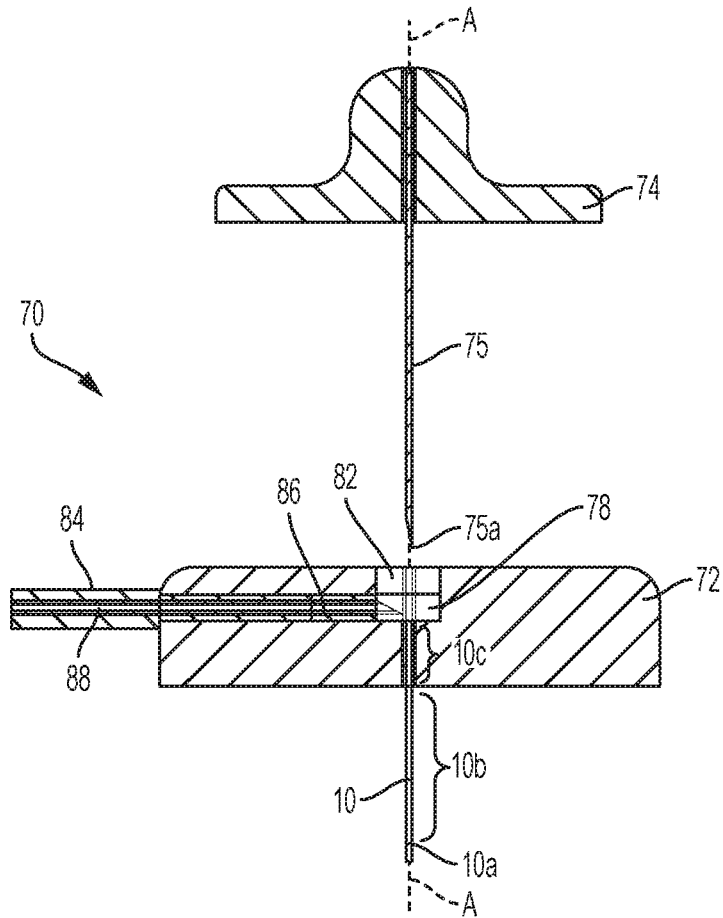


FIG. 20

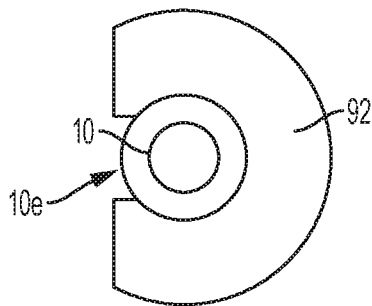


FIG. 21

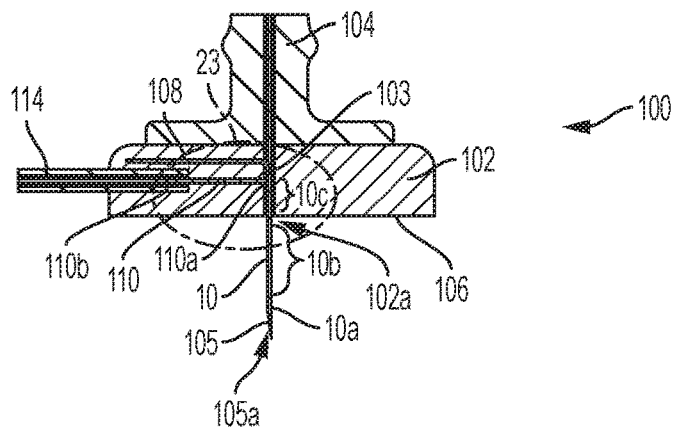


FIG. 22

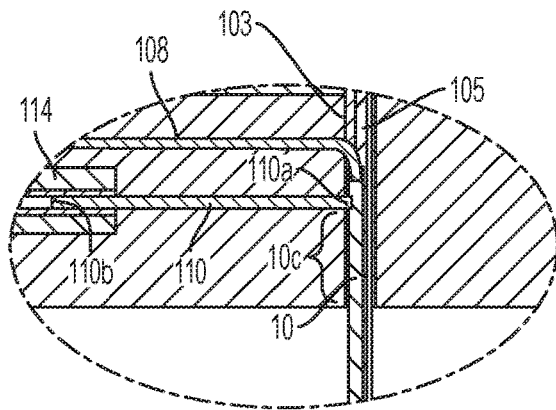


FIG. 23

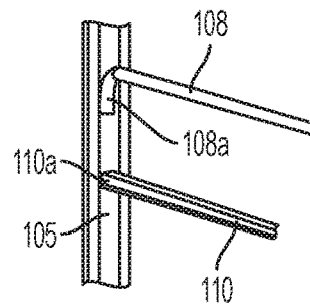


FIG. 24

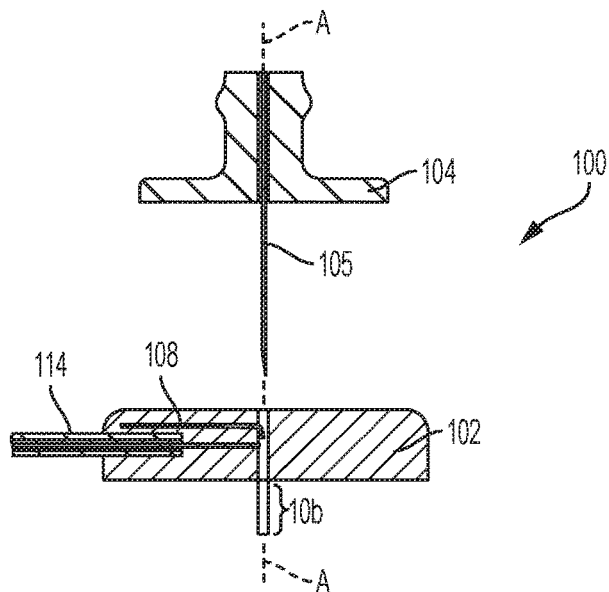


FIG. 25

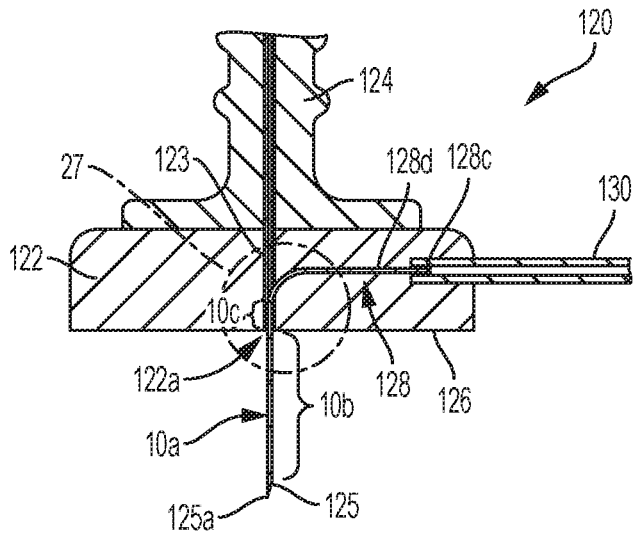


FIG. 26

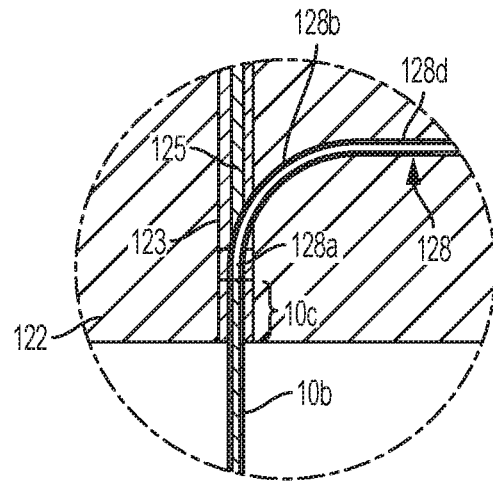


FIG. 27

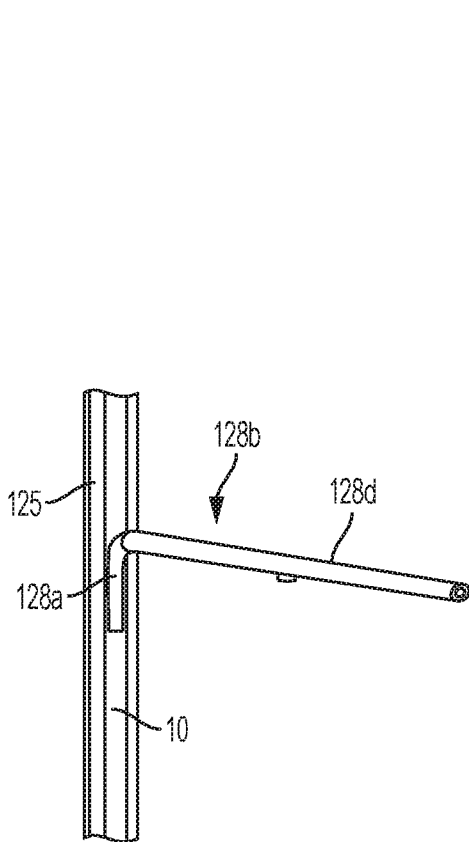


FIG. 28

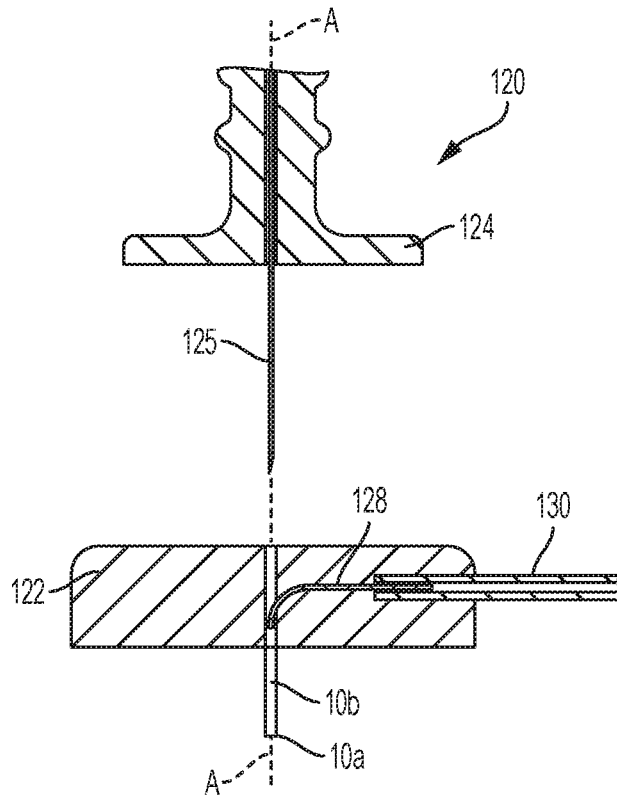


FIG. 29

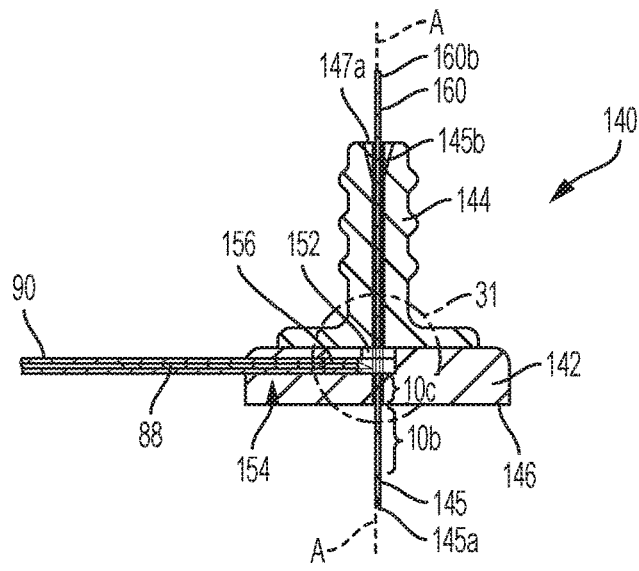


FIG. 30

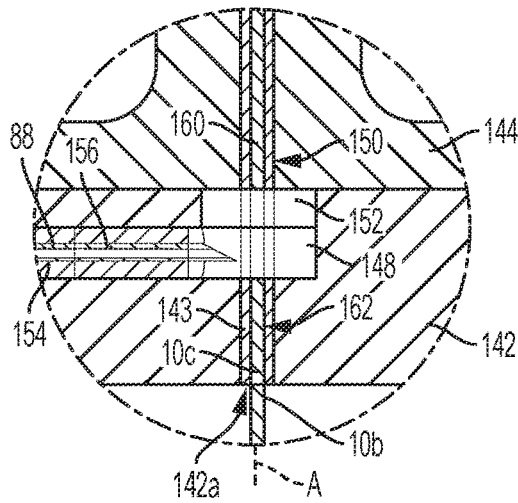


FIG. 31

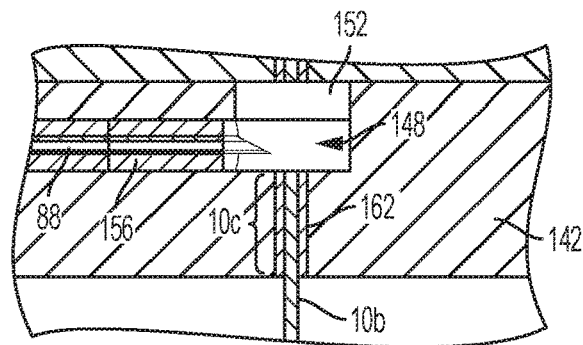


FIG. 32

1

FLEXIBLE CANNULA INSERTION DEVICE, SYSTEM AND PROCESS

CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

This application claims priority from Provisional U.S. Application 62/503,274, filed May 8, 2017, which is incorporated herein by reference in its entirety.

BACKGROUND

Various types of modern medical devices include or employ flexible tubing for conveying fluid media through a flow passage in the tubing. Such flexible tubing may be employed for conveying fluid media to or from a patient, a sensor, a pump, an insertion set or other medical device, a reservoir or fluid container, an implanted or partially implanted device, or the like. Such flexible tubing may be included in a sensor, a pump, in insertion set or other medical device. In addition, flexible tubing may be employed for forming a cannula configured to be inserted into or partially into a patient, for example, through the patient's skin.

Certain diseases or conditions may be treated, according to modern medical techniques, by delivering a medication or other substance to the body of a user, through a cannula or other tubing, either in a continuous manner or at particular times or time intervals within an overall time period. For example, diabetes is commonly treated by delivering defined amounts of insulin to the user at appropriate times. Some common modes of providing insulin therapy to a user include delivery of insulin through manually operated syringes and insulin pens. Other modern systems employ programmable fluid infusion devices (e.g., insulin pumps) to deliver controlled amounts of insulin to a user. In certain instances, these fluid infusion devices employ an insertion set, such as an infusion set, to be coupled to the body of a user for the delivery of the insulin. Typically, the infusion set includes a portion of a cannula that can be, for example, inserted under the skin of the user to deliver controlled amounts of infusion media (e.g., insulin) to the user.

Alternatively or in addition, an insertion set with a cannula may be configured or employed as a sensor set, to couple a sensor to a body of the user. For example, a sensor set may be configured to monitor glucose levels with a sensor set, to measure glucose levels in blood or interstitial fluid.

In certain contexts of use, it may be desirable to employ tubing that is relatively highly flexible or bendable, such that the tubing may be curved or bent during use. During installation or use, forces may be applied to the tubing that cause it to curve or bend. However, as shown in demonstration diagram of FIG. 1, when a compressive force F is applied along a length L of typical conventional tubing **1**, the tubing **1** can tend to buckle or kink at a bend location **3** of the tubing. In FIG. 1, the tubing **1** extends from a structure **2**, such as a base of an infusion set or another medical device housing, to a surface S . When the force F is applied (for example, by moving the medical device housing toward the surface S , the tubing **1** is caused to bend and kink at a bend location **3**. More specifically, at the bend location **3**, the tubing wall has collapsed inward, resulting in a reduction in the width or diameter of the flow passage in the tubing. Such kinking or collapsing of the wall of the flexible tubing can limit or cut off fluid-flow through the flow passage, which

2

can adversely affect the operation or function of the medical device or system employing the tubing.

To avoid kinking or collapsing during insertion or use of a flexible tubing cannula and to improve patient comfort during insertion, an insertion needle may be extended through the flexible tubing cannula, as shown in FIGS. 2 and 3. In FIGS. 2 and 3, the needle **4** extends through the flexible tubing cannula **1** and supports the flexible tubing from bending during insertion into a patient's skin, septum or other structure. FIG. 3 shows the flexible tubing cannula **1** and the needle **4**, as viewed in the cross-section 3-3 of FIG. 2.

The needle **4** has an end **4a** that extends out from a distal end of the flexible tubing cannula **1**, for piercing the patient's skin (or septum or other structure), during insertion of the flexible tubing cannula **1**. Once the needle end **4a** and a portion of the length of the cannula **1** have been inserted into the patient's skin (or septum or other structure), the needle **4** may be withdrawn from the flexible tubing cannula **1**, to leave the distal end of the flexible tubing cannula **1** in the patient (or through the septum or other structure). Accordingly, in FIGS. 2 and 4, the flexible tubing cannula **1** must have a sufficiently large width or diameter, to be arranged on the outside of the needle **4**. As a representative example, certain infusion set cannulas **1** have an outside diameter corresponding to a gauge of 23 G (or about 0.025-0.0255 in), and certain insertion needles **4** have an outside diameter of a gauge of 27 G or 28 G (or about 0.014 in.-0.0165 in). The distal end **1a** of the cannula **1** may be formed with a taper, which can add to manufacturing steps and costs.

In certain contexts and applications of use, it may be desirable to reduce or minimize the size of the outer diameter of the flexible tubing, while still providing sufficient fluid flow capacity through the tubing. In addition, it may be desirable for the tubing to have a relatively high degree of flexibility, but also withstand kinking or buckling when bent or curved. In addition, it may be desirable to form cannula with a relatively thin, flexible tubing. A thin, flexible tubing can improve patient comfort during insertion and use of the cannula.

SUMMARY

One or more examples and aspects described herein relate to an insertion set device or system, or other medical devices or systems, that include or employ a flexible tubing cannula. Certain examples include or employ a cannula formed of a kink resistant fluid flow tubing. Particular examples and aspects described herein relate to a medical device including a flexible tubing cannula and a hollow insertion needle having a channel in which the tubing is received for insertion into a patient, septum or other structure.

According to an example, an insertion set system includes a base configured to be secured to a patient. A flexible tubing is supported by the base and has a distal end portion located external to the base. The distal end portion forms a cannula that is configured to be inserted into the patient, when or while the base is secured to the patient. The insertion set system also includes an inserter having a needle. The needle has a needle channel in which at least the distal end portion of the flexible tubing is received. The needle is able to slide relative to the flexible tubing, to selectively withdraw the needle off of at least the distal end portion of the flexible tubing.

In a further example of the above-described insertion set system, the needle and the flexible tubing are in a first state

3

in which at least the distal end portion of the flexible tubing is received in the needle channel, and the needle is moveable along a length dimension of the distal end portion of the flexible tubing to a second state in which the needle is separated from the distal end portion of the flexible tubing.

A further example of the above-described insertion set system includes a fluid coupling, wherein the flexible tubing has a second end opposite the distal end portion, and wherein the second end of the flexible tubing is connected in fluid flow communication with a fluid coupling.

In a further example of the above-described insertion set system, the needle of the inserter has a length dimension and a slot-shaped opening extending along at least a portion of the length dimension, the slot-shaped opening being open to the needle channel. In addition, the flexible tubing includes a length portion extending from the distal end portion to the second end of the flexible tubing, the length portion extending out of the needle channel, through the slot-shaped opening of the needle.

In a further example of the above-described insertion set system, the length portion of the flexible tubing that extends out of the needle channel has a bend of between about 90° and about 160° (or, in particular examples, between about 135° and about 160°) relative to an axial dimension A.

In a further example of the above-described insertion set system, the slot shaped opening in the needle has a first width extending from a distal end of the needle, along a first portion of the length dimension of the needle, and a second width extending along a second portion of the length dimension of the needle, the second width being larger than the first width.

In a further example of the above-described insertion set system, the distal end portion of the flexible tubing has a length extending along an axial dimension of the flexible tubing. In addition, the base has a chamber in fluid flow communication with the flexible tubing. In addition, the base has a channel extending transverse to the axial dimension, through which fluid may flow to or from the chamber.

In a further example of the above-described insertion set system, the channel in the base extends from the chamber at an angle of between about 90° and about 160° (or, in particular examples, between about 135° and about 160°) relative to the axial dimension A of the distal end portion of the flexible tubing.

A further example of the above-described insertion set system includes a first septum on the base, at a location in alignment with the axial dimension of the flexible tubing and the chamber, wherein the needle extends through the first septum and the chamber, when the distal end portion of the flexible tubing is received in the needle channel.

A further example of the above-described insertion set system includes a second septum located in the channel or between the channel and the chamber, the second septum configured to be pierced by a further needle for connection of a further tubing to the channel.

In a further example of any of the above-described insertion set systems the flexible tubing has a further length portion extending from the distal end portion into the base. In addition, the base includes a needle channel through which the further length portion of the flexible tubing extends, and a collar fixing the further length portion of the flexible tubing to the base within the needle channel of the base, wherein the needle is pierced through the collar when the distal end portion of the flexible tubing is received in the needle channel.

In a further example of the above-described insertion set system, the flexible tubing has a further length portion

4

extending from the distal end portion into the base. In addition, the example insertion set system further includes a holding pin arranged and configured to abut an end portion of the further length portion of the flexible tubing and inhibit movement of the flexible tubing with the needle while the needle is being withdrawn off of the distal end portion of the flexible tubing. The holding pin is moveable away from the end portion of the further length of the flexible tubing, after the needle has been withdrawn off of the distal end portion of the flexible tubing.

In a further example of the above-described insertion set system, the distal end portion of the flexible tubing has a length extending along an axial dimension of the flexible tubing. In addition, the flexible tubing has a further length portion extending from the distal end portion into the base. In addition, the insertion set system further includes a holding pin arranged and configured to abut an end portion of the further length portion of the flexible tubing and inhibit movement of the flexible tubing with the needle while the needle is being withdrawn off of the distal end portion of the flexible tubing.

In a further example of the above-described insertion set system, the holding pin comprises a rigid wire or stop structure that is fixed to the base.

In a further example of the above-described insertion set system, the needle of the inserter has a length dimension and a slot-shaped opening extending along at least a portion of the length dimension, the slot-shaped opening being open to the needle channel. In addition, the holding pin extends out of the needle channel, through the slot-shaped opening of the needle.

In a further example of the above-described insertion set system, the flexible tubing has a further length portion extending from the distal end portion into the base. In addition, the insertion set system further includes a rigid hollow tube connected in fluid flow communication with an end portion of the further length portion of the flexible tubing and abutting the end portion of the further length portion of the flexible tubing to inhibit movement of the flexible tubing with the needle while the needle is being withdrawn off of the distal end portion of the flexible tubing.

In a further example of the above-described insertion set system, the needle of the inserter has a length dimension and a slot-shaped opening extending along at least a portion of the length dimension, the slot-shaped opening being open to the needle channel. In addition, the rigid hollow tube has a length portion that extends out of the needle channel, through the slot-shaped opening of the needle.

In a further example of the above-described insertion set system, the rigid hollow tube is fixed to the base and is configured to be connected in fluid flow communication with a further tubing located at least partially external to the base.

An example of a method of making an insertion set system includes providing a base configured to be secured to a patient, and supporting a flexible tubing supported by the base, with a distal end portion of the flexible tubing located external to the base, the distal end portion forming a cannula that is configured to be inserted into the patient, when or while the base is secured to the patient. The method further includes receiving by the base, an inserter having a needle, the needle having a needle channel. The method further includes receiving at least the distal end portion of the flexible tubing in the channel for sliding movement, wherein the needle is able to slide relative to the flexible tubing, to selectively withdraw the needle off of at least the distal end portion of the flexible tubing.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other aspects and features of the present invention will become more apparent to those skilled in the art from the following detailed description of the example embodiments with reference to the accompanying drawings, in which:

FIG. 1 is a cross-section view of a PRIOR ART tubing having a kink or buckle.

FIG. 2 is a cross-section view of the PRIOR ART tubing of FIG. 1, on an insertion needle.

FIG. 3 is a cross-section view of the tubing and insertion needle taken at 3-3 of FIG. 2.

FIG. 4 is a cross-section view of a flexible tubing according to an example embodiment.

FIG. 5 is a perspective view of a length of a flexible tubing according to an example embodiment.

FIG. 6 is a cross-section view of the flexible tubing of FIG. 5, within an insertion needle.

FIG. 7 is a cross-section view of the tubing and insertion needle taken at 7-7 of FIG. 6.

FIG. 8 is a cross-section view of the tubing and insertion needle taken at 8-8 of FIG. 6.

FIG. 9 is a flow chart of a method of using a tubing and insertion needle of FIG. 6.

FIG. 10 is a cross-section view of an example insertion set device in a first state.

FIG. 11 is a top view of the example insertion set device of FIG. 10.

FIG. 12 is a further cross-section view of the example insertion set device of FIG. 10 transitioning to a second state.

FIG. 13 is a further cross-section view of the example insertion set device of FIG. 10 in the second state.

FIG. 14 is a partial exploded, perspective view of a base of the example insertion set device of FIG. 10.

FIG. 15 is a partial perspective view of a slotted needle of the example insertion set device of FIG. 10.

FIG. 16 is a flow chart of a process for making an insertion set device.

FIG. 17 is a cross-section view of another example insertion set device in a first state.

FIG. 18 shows an enlarged view of a portion of FIG. 17 identified by the circle labeled 18 in FIG. 17.

FIG. 19 is a cross-section view of the flexible tubing, the slotted inserter needle and the collar of the example insertion set device of FIG. 17, taken perpendicular to the axial dimension A.

FIG. 20 is a cross-section view the example insertion set device of FIG. 17, in a second state.

FIG. 21 is a cross-section view of the flexible tubing, the slotted inserter needle and the collar of the example insertion set device of FIG. 20, taken perpendicular to the axial dimension A.

FIG. 22 is a cross-section view of another example insertion set device in a first state.

FIG. 23 shows an enlarged view of a portion of FIG. 22 identified by the circle labeled 23 in FIG. 22.

FIG. 24 shows another enlarged view of features in FIG. 23.

FIG. 25 is a cross-section view the example insertion set device of FIG. 22, in a second state.

FIG. 26 is a cross-section view of another example insertion set device in a first state.

FIG. 27 shows an enlarged view of a portion of FIG. 26 identified by the circle labeled 27 in FIG. 26.

FIG. 28 shows another enlarged view of features in FIG. 27.

FIG. 29 is a cross-section view the example insertion set device of FIG. 26, in a second state.

FIG. 30 is a cross-section view of another example insertion set device in a first state.

FIG. 31 shows an enlarged view of a portion of FIG. 30 identified by the circle labeled 31 in FIG. 30.

FIG. 32 shows another enlarged view of features in FIG. 31, in a second state.

DETAILED DESCRIPTION

Hereinafter, example embodiments will be described in more detail with reference to the accompanying drawings. The present invention, however, may be embodied in various different forms, and should not be construed as being limited to only the illustrated embodiments herein. Rather, these embodiments are provided as examples so that this disclosure will be thorough and complete, and will fully convey the aspects and features of the present invention to those skilled in the art. Accordingly, processes, elements, and techniques that are not necessary to those having ordinary skill in the art for a complete understanding of the aspects and features of the present invention may not be described. Unless otherwise noted, like reference numerals denote like elements throughout the attached drawings and the written description, and thus, descriptions thereof may not be repeated. Further, features or aspects within each example embodiment should typically be considered as available for other similar features or aspects in other example embodiments.

Certain terminology may be used in the following description for the purpose of reference only, and thus are not intended to be limiting. For example, terms such as “top”, “bottom”, “upper”, “lower”, “above”, and “below” could be used to refer to directions in the drawings to which reference is made. Terms such as “front”, “back”, “rear”, “side”, “outboard”, and “inboard” could be used to describe the orientation and/or location of portions of the component within a consistent but arbitrary frame of reference which is made clear by reference to the text and the associated drawings describing the component under discussion. Such terminology may include the words specifically mentioned above, derivatives thereof, and words of similar import. Similarly, the terms “first”, “second”, and other such numerical terms referring to structures do not imply a sequence or order unless clearly indicated by the context.

It will be understood that when an element or feature is referred to as being “on,” “connected to,” or “coupled to” another element or layer, it can be directly on, connected to, or coupled to the other element or feature, or one or more intervening elements or features may be present. In addition, it will also be understood that when an element or features is referred to as being “between” two elements or features, it can be the only element or feature between the two elements or features, or one or more intervening elements or features may also be present.

The terminology used herein is for the purpose of describing particular embodiments and is not intended to be limiting of the present invention. As used herein, the singular forms “a” and “an” are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms “comprises,” “comprising,” “includes,” and “including,” “has,” “have,” and “having,” when used in this specification, specify the presence of the stated features, integers, steps, operations, elements,

and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. As used herein, the term “and/or” includes any and all combinations of one or more of the associated listed items. Expressions such as “at least one of,” when preceding a list of elements, modify the entire list of elements and do not modify the individual elements of the list.

As used herein, the term “substantially,” “about,” and similar terms are used as terms of approximation and not as terms of degree, and are intended to account for the inherent variations in measured or calculated values that would be recognized by those of ordinary skill in the art. Further, the use of “may” when describing embodiments of the present invention refers to “one or more embodiments of the present invention.” As used herein, the terms “use,” “using,” and “used” may be considered synonymous with the terms “utilize,” “utilizing,” and “utilized,” respectively.

Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the present invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the relevant art and/or the present specification, and should not be interpreted in an idealized or overly formal sense, unless expressly so defined herein.

Various types of modern medical devices and cannulas include or employ flexible tubing for conveying fluid media. A flexible tubing for conveying fluid media and medical devices and systems that include such flexible tubing are described, where the flexible tubing is configured with a relatively small outer diameter, a relatively high degree of flexibility and a relatively high resistance to kinking or buckling. In certain examples, the flexible tubing forms a cannula configured to be inserted into or partially into a patient, such as, through the patient’s skin. The flexible tubing cannula may be included in an insertion set or other medical device or system. Accordingly, in certain examples, a flexible tubing as described herein is included in an insertion set, an infusion set, a sensor device, an infusion pump or other fluid delivery system, or the like.

Also as described herein, a flexible tubing according to certain examples described herein may be configured to fit inside of a hollow needle, for insertion into a patient, septum or other structure. In contrast to prior arrangements in which a tubing is arranged on the outside of an insertion needle (as represented in FIGS. 2 and 3), a flexible tubing according to certain examples described herein may have a sufficiently small outer diameter, to fit within an open channel of an insertion needle.

Therefore, according to certain examples described herein, a flexible tubing is configured with a reduced or minimized outer diameter (relative to certain conventional medical tubing), while still providing sufficient fluid flow capacity through the tubing, a relatively high degree of flexibility, and a resistance to kinking or buckling when bent or curved. For example, a cannula formed from a thin, flexible tubing may have a reduced or minimized outer diameter and relatively high flexibility (without kinking or buckling) for improved patient comfort.

A relatively high degree of flexibility in the tubing, without kinking or buckling, can allow the tubing to bend and curve, which can improve the ability of the tubing to be configured, fitted or adjusted in a medical device or system. Also, a flexible tubing cannula having thin outer dimension

and a relatively high degree of flexibility can improve patient comfort, by minimizing insertion trauma and allowing the cannula to flex with movement of the patient.

A flexible tubing for a medical device or system described herein may have an axial length dimension and a generally circular cross-section shape taken perpendicular to the axial length dimension, and a central passage through which fluid may flow. In other examples, the tubing may have a cross-section shape that is not a circle, such as, but not limited to an oval, another curved shape, a polygon or a shape having a combination of curved and straight edges. The cross-section shape of the central passage may have a circular or another shape, and may correspond to (be the same shape as) the outer cross-section shape of the tubing. In other examples, the cross-section shape of the central passage may be a different shape relative to the outer cross-section shape of the tubing.

The material of the flexible tubing is compatible with fluids intended to be conveyed through the tubing, and with other materials to which the tubing may come into contact or be connected, in the intended environment of use. In certain examples, the flexible tubing is made of a material that is biologically compatible, for use in contexts in which the flexible tubing is in contact or connected with a biological entity (such as a human patient or another biological entity), or is implanted fully or partially in the patient (or other biological entity). In certain examples, the flexible tubing is treated in one or more processes for enhancing biological compatibility or other compatibility for an intended environment or use, such as, but not limited to cleaning, sterilizing, treating, or coating with Heparin, or other anticoagulant, an antibiotic, nitric-oxide or other materials, or the like.

In certain examples the tubing is made of a material that is suitable for medical uses, including but not limited to materials compatible with, and suitable for, implanting or partially implanting into a patient or other biological entity. Alternatively or in addition, the tubing material is selected to be compatible with and suitable for conveying one or more desired or predefined fluids (such as, but not limited to insulin, cancer or AIDs treatment drugs, or other medications, drugs or therapy fluids). Such materials may include, but are not limited to a polyether block amide (PEBA) of thermoplastic elastomer (TPE) such as PEBAX™, a polytetrafluoroethylene (PTFE), an ethylene tetrafluoroethylene (ETFE), a thermoplastic polyurethane (TPU) such as PELLETAN™, or the like. However, for other contexts and applications of use, the tubing may be made of other materials suitable and compatible with those contexts and applications. The tubing may be made by any suitable manufacturing process including, but not limited to extrusion, molding, machining or the like.

An example of a flexible tubing **10** having a circular cross-section shape defining an axial dimension **A**, is shown in FIGS. 4 and 5. In FIG. 4, the flexible tubing **10** extends from or through a housing or other structure of a medical device **12**, and has a length portion that is bent. In FIG. 5, a length **L** of the flexible tubing **10** is shown.

The flexible tubing **10** has a central channel or passage **14**, through which fluid may flow. The fluid flow passage **14** extends along the length **L** of the tubing **10**, and shares the same axis **A** of the tubing **10**. As shown in FIG. 5, the tubing **10** has an outer peripheral surface **16**, an inner surface (the outer surface of the fluid flow passage **14**), and a thickness **t** between the outer peripheral surface **16** and the inner surface (outer surface of the fluid flow passage **14**). The

tubing **10** has an inner radius r (the radius of the fluid flow passage **14**) and an outer radius R (the radius of the outer peripheral surface **16**).

In certain examples, the flexible tubing **10** is configured to have a relatively high L/R length-to-outer-radius ratio (or slenderness ratio), to be sufficiently flexible and kink resistant. In certain examples, the ratio R/r (between the outer radius R and the inner radius r) is increased or maximized, to increase the flexibility of the tubing **10**. In particular examples, the L/R is selected to be sufficiently high (in dimensions suitable for the context of use) to increase or maximize the kink resistance of the tubing, and also the ratio R/r is selected to be sufficiently high (in dimensions suitable for the context of use), to increase or maximize the flexibility of the tubing.

In addition to increasing or maximizing one or both of the ratios L/R and R/r of the tubing (in dimensions suitable for the context of use of the tubing), it may be beneficial for certain applications of use to reduce or minimize the outer radius R of the flexible tubing, while still allowing for sufficient fluid flow volume or pressure (or both). A thinner tubing may be able to fit into narrow spaces such as, but not limited to an inner passage of a hollow needle. A thinner tubing may provide a more comfortable cannula or other implantable or partially implantable device. Also, if the slenderness ratio L/R is too small, the tubing can have a tendency to kink or buckle along the length L .

Accordingly, in particular examples, a relatively thin tubing that is both flexible and resistant to kinking is configured of a PEBAX, PTFE, or other suitable material, and has an L/R ratio that is equal to or greater than 34.8. Alternatively or in addition, the tubing has an R/r ratio that is equal to or greater than 1.5. In particular examples, the L/R ratio is between about 34.889 and about 78.667. In particular examples, the R/r ratio is between about 1.5 and about 1.8.

A flexible tubing having such dimensions can have an improved flexibility and resistance to kinking or buckling, as compared to typical medical grade tubing and cannula tubing. In addition, a flexible tubing having such dimensions may be configured relatively thin, for example, with an outer radius of about 0.0045 inch (0.1143 mm) or less.

Thus, in certain examples, a tubing **10** made of a PEBA or other TPE such as PEBAX™, or a PTFE (or a combination of those materials) has an outer radius of about 0.1143 mm. (0.0045 inch) and, thus, has an inner radius of about 0.127 mm. (0.0025 inch) (applying the above-noted R/r ratio of 1.8), and a length (or length portion) L in the range of about 6 mm. to about 9 mm. (applying the above L/R ratio ranges), as shown in Table 1. In other examples, the outer radius is about 0.1143 mm. (0.0045 inch) and the inner radius is about 0.0762 mm. (0.003 inch) (applying the above-noted R/r ratio of 1.5, and a length (or length portion) L in the range of about 4 mm. to about 5 mm. (applying the above L/R ratio ranges), as shown in Table 1.

TABLE 1

Length	R	r	L/R	R/r
4 mm. (0.157 inch)	0.1143 mm. (0.0045 inch)	0.0762 mm. (0.003 inch)	34.889	1.50
5 mm. (0.197 inch)	0.1143 mm. (0.0045 inch)	0.0762 mm. (0.003 inch)	43.778	1.50
6 mm. (0.236 inch)	0.1143 mm. (0.0045 inch)	0.127 mm. (0.0025 inch)	54.444	1.80
9 mm. (0.354 inch)	0.1143 mm. (0.0045 inch)	0.127 mm. (0.0025 inch)	78.667	1.80

In the table 1 examples, the tubing **10** can be relatively flexible, while having a relatively high resistance to kinking or buckling (collapsing of the outer wall) when bent along a length portion of length L .

In addition, the flexible tubing **10** can be configured relatively thin (can have a relatively small outer diameter). By reducing or minimizing the size of the outer diameter of the flexible tubing **10**, various advantages are available such as, but not limited to improving patient comfort, and reducing the size and the weight of a medical device or system that includes the tubing.

In certain examples as shown in FIGS. 6 and 7, the flexible tubing **10** is configured to be sufficiently thin, to extend through a central channel of a hollow insertion needle **20**. FIG. 7 shows the flexible tubing and the insertion needle **20**, as viewed in the cross-section 7-7 of FIG. 6. The insertion needle **20** has a hollow, central channel configured to receive the flexible tubing **10**. When the flexible tubing **10** is received within the hollow channel of the insertion needle **20**, the insertion needle **20** and flexible tubing **10** are moveable relative to each other in the axial direction A , for example, to allow the needle to slide off of the flexible tubing **10**, or to allow the flexible tubing to slide out of the needle **30**.

In particular examples, a cannula composed of the flexible tubing **10** can be received within the channel of the hollow needle **20**, with the distal end **10a** of the flexible tubing **10** located at least partially inside of the channel of the hollow needle **20** as shown in FIGS. 6 and 7. When the flexible tubing **10** is received in the channel, the needle **20** is slidable relative to the flexible tubing **10**, in the axial direction. In that arrangement, the hollow needle **20** may be inserted into a patient's skin (or a septum or other structure), a sufficient distance to place the distal end of the flexible tubing **10** in the patient (or through the septum or other structure). The hollow needle **20** provides additional rigidity and can have a pointed or sharp tip, to assist in piercing the patient's skin (or septum or other structure) during insertion. Once the hollow needle **20** containing the flexible tubing **10** is inserted into (or partially into) the patient's skin (or a septum or other structure), the hollow needle **20** may be slid off of some or all of the flexible tubing **10**, while leaving the distal end **10a** of the flexible tubing **10** in place in the patient (or through the septum or other structure).

By locating a cannula composed of flexible tubing **10** inside of the hollow needle **20**, various advantages are available such as, but not limited to reducing insertion force needed to insert the cannula and improving patient comfort. In addition, the distal end **10a** of the flexible tubing **10** need not be tapered, which can help to reduce or minimize manufacturing costs as compared to tapered tubing. Also, a straight cylindrical tip, without taper, can more evenly distribute compression stresses compared to tubing configurations with a tapered distal end.

In the example of FIGS. 6 and 7, the distal end portion **20a** of the needle **20** has a slot or opening along the axial dimension A of the side wall of the needle. Accordingly, the cross-section shape of the distal end portion **20a** of the needle (at the cross-section 7-7 in FIG. 6) has a slotted circle or "C" shape, as shown in FIG. 7. The slot or opening in the side wall of the needle **20** extends from the distal end **20b** of the needle **20**, along at least a portion of the axial length of the needle **20**. Accordingly, when the needle **20** is moved in the axial direction relative to the tubing **10**, to slide off (or partially off) of the tubing **10**, the distal end portion **20a** of

the needle **20** may be slid off of at least a portion of the tubing **10**, leaving the distal end **10a** of the tubing **10** outside of the needle **20**.

In the example in FIG. **6**, the slot or opening in the side wall of the needle **20** extends a portion, but not the entire axial length of the needle **20**, such that a cross-section shape of the needle **20** at **8-8** in FIG. **6** has a shape as shown in FIG. **8**, where that section of the needle has a fully cylindrical shape. In other examples, the slot or opening in the side wall of the needle **20** extends the entire axial length (or substantially the entire axial length) of the needle **20**, such that a cross-section shape of the needle **20** is similar to that shown in FIG. **7**, along the entire (or substantially the entire) axial length of the needle **20**. In further examples, the hollow needle **20** may have a small opening or slot at its distal end (or sharp end) through which the distal end portion of the flexible tubing **10** may extend as the needle **20** is withdrawn, but has a full cylindrical shape (with a cross section shape as shown in FIG. **8**) along the rest of the length of the needle.

An example process **30** of using a flexible tubing cannula is described with reference to FIG. **9**. The process **30** includes receiving a tubing in a needle (at **32**). The tubing may be received in a channel of a needle as described herein with respect to the flexible tubing **10** received within the central channel of the slotted needle **20**.

The process **30** also includes inserting the needle and tubing (at **34**). The needle and tubing may be inserted into a patient, septum or other structure, as described herein with respect to inserting the needle **20** while the tubing **10** is located within the central channel of the needle **20**.

The process **30** also includes withdrawing the needle while the tubing is held in an inserted state (at **36**). The needle may be slid off of the tubing as described herein with respect to sliding the needle **20** in the axial direction relative to the tubing **10**.

The process **30** also includes coupling the tubing to a device, fluid source or a fluid receptacle (at **38**). For example, the tubing may be coupled to a medical device, a fluid source or a fluid receptacle at any stage of the process **30**. In certain examples, the tubing has a second end (or port) coupled to a fluid source, for receiving fluid to be conveyed through the tubing to a patient (or device to which the distal end of the tubing is connected). The fluid source may include, but is not limited to an infusion pump, fluid-containing reservoir, or other fluid delivery system. In other examples, the second end (or port) of the tubing may be coupled to a reservoir or volume for receiving fluid from the patient (or from the device to which the distal end of the tubing is connected). For example, the reservoir or volume may be a portion of a sensor that receives fluid from a patient (or from a device) and senses detectable parameters of the fluid.

In other examples, a flexible tubing **10** or a hollow needle **20** with a flexible tubing **10** may be employed in other suitable processes. In systems, devices and process in which the flexible tubing **10** is received within the central channel of the hollow needle **20** for insertion, various advantages may be available, including but not limited to an ability to minimize or reduce the outer diameter of the flexible tubing **10** (for example, relative to a tubing and inserter configuration of FIGS. **1-3**, which can significantly improve patient comfort during insertion and use when the flexible tubing **10** forms a cannula. In addition, the flexible tubing **10** may have a single, constant diameter, which can reduce manufacturing costs and improve patient comfort. Also, stress on the flexible tubing **10** before and during insertion may be reduced or minimized (for example, relative to a tubing and

inserter configuration of FIGS. **1-3** in which the tubing **1** is located on the outside of the inserter needle **4**).

Further examples of slotted needle configurations, insertion sets and other medical devices that include or employ slotted needles are described with reference to FIGS. **10-32**. The systems and devices in FIGS. **10-32** may include or employ a kink resistant, flexible tubing **10** as described herein with reference to FIGS. **4-8**. However, other examples of such systems and devices may employ other suitable tubing or flexible tubing. The insertion sets may be infusion sets configured to couple to (or be part of) an infusion system for delivering a fluid media to a patient or other entity, through the flexible tubing, for example, from an infusion pump, reservoir or other delivery device. Alternatively or in addition, the insertion sets may be configured to couple to (or be part of) a sensor system for delivering a fluid media from a patient or another entity, through the flexible tubing, for example, to a sensing device. In other examples, the insertion sets may be configured to couple to (or be part of) other systems that deliver fluid media to or from a patient or another entity.

An example of an insertion set device **40** having a cannula formed with or of a flexible tubing **10** (or other suitable tubing) is described with reference to FIGS. **10-14**. FIGS. **10** and **11** show a cross-section side view and a top view, respectively, of the insertion set device **40**, in a first state. The cross-section view in FIG. **10** is taken along **10-10** of FIG. **11**. FIG. **12** shows a similar cross-section view of the insertion set device **40**, transitioning from the first state to a second state. FIG. **13** shows a similar cross-section view of the insertion set device **40**, in the second state.

The insertion set device **40** includes a base **42** and an inserter **44**. In the first state, as shown in FIGS. **10** and **11**, the inserter **44** is received and supported by the base **42**, but is removable from the base **42** by moving the inserter **44** (e.g., lifting upward in FIG. **10**) from the base **42** in the axial direction A (or otherwise moving the inserter **44** and base **42** apart in the axial direction A). In FIG. **12**, the inserter **44** is partially lifted from the base **42**. In the second state, as shown in FIG. **13**, the inserter **44** is fully separated (fully lifted) from the base **42**.

The base **42** has a surface **46** configured to abut against or secure to the skin of a patient, or to a surface of a septum or other device to which the cannula of flexible tubing **10** is to be inserted. In particular examples, one or more mechanisms for securing the surface **46** to the patient, septum or other device may be included on the base **42**, such as, but not limited to adhesive on the surface **46**, straps, suture tabs or openings, or the like.

The base **42** may include one or more parts that form a housing for holding or containing the flexible tubing **10** and a coupling **48**. In the example of FIG. **14**, the base **42** includes two parts that may be separated to allow access to internal components, and that couple together to form a disc-shaped housing that contains the internal components. Any suitable mechanism may be employed to couple the base parts together to form the housing of the base **42**, including, but not limited to shaft protrusions **43** on one part that fit into corresponding apertures in another part, in a friction-fit manner. Alternatively or in addition, other suitable mechanism may be employed to couple the base parts together, including, but not limited to adhesives, screws or other threaded fasteners, friction fitted groove and rib configurations, or the like. In other examples, the base **42** may include a single part housing, or more than two parts that form a housing, the housing may have other suitable disc or non-disc shapes, and other suitable connection structures

13

may be employed for connecting the housing parts. In yet other examples, the base 42 may have a be configured with a hollow or partially hollow interior, for example, in a clamshell configuration. In other examples, the base 42 may have other suitable configurations that holds and encloses a portion of the flexible tubing 10 and a portion of the coupling 48.

The base 42 shown in FIGS. 10-14 has a generally rounded disc shape, with a rounded top edge. However, in other examples, the base 42 may have other suitable shapes. The base 42 may be made of any suitable material, such as, but not limited to plastic, metal, ceramic, composite material, or the like. In particular examples, the base 42 is a generally rigid structure. In other examples, the base 42 may have sufficient rigidity to hold its shape, but may be made of material having some flexibility or malleability, such as but not limited to a soft plastic, a rubber or rubber-like material, or the like.

The base 42 has a first opening 42a in the surface 46 (the bottom surface in FIGS. 10-14) and includes a needle passage 50 extending from the first opening 42a, to a second opening 42b in a surface of the base 42 (the top surface in FIGS. 10-14) opposite to the surface 46. The passage 50 may be formed as a channel or bore through the material of the base 42 as shown in FIG. 14. In further examples, the passage 50 may be the interior channel of a tube-like structure in the base 42, extending between the first and second openings 42a and 42b.

The distal length portion 10b of the tubing 10 extends out from the first opening 42a in the surface 46 of the base 42, such that the distal end 10a of the tubing 10 is located outside of the base 42. A further length portion 10c of the tubing 10 is located within the base 42 and extends from the distal length portion 10b, to the coupling 48. The further length portion 10c has a tubing end that is connected in fluid flow communication with the coupling 48.

The further length portion 10c of the flexible tubing 10 has a first section that extends along part of the length of the passage 50, a second section that forms a relatively sharp bend 10d and a third section that extends from the bend 10d to the coupling 48. The bend 10d may form a relatively sharp angle, such that the height H in the axial dimension of the base 42 (dimension between the surface 46 and the opposite facing surface) may be made relatively small or minimized. In certain examples, the bend 10d may be about 90°, such that the coupling 48 is directed about 90° from the direction of distal length portion 10b of the tubing 10. This arrangement allows a further tubing 52 to be connected to the coupling 48, external to the base 42, and extend outward from the base 42 in a direction substantially parallel to and along the surface of the patient's skin (or other surface) to which the base 42 secures. Accordingly, the base 42 and tubing 52 may be more easily concealed under clothing or the like. In other examples, the bend 10d may be between about 90° and about 160° (or, in particular examples, between about 135° and about 160°) relative to the axial dimension A.

In certain system examples, the further tubing 52 may be connected or configured to connect (at an end opposite to the end connected to the coupling 48) to an infusion pump or other fluid delivery device, a sensor or monitoring device, or the like. In certain examples, the further tubing 52 may have a tubing configuration as described herein with reference to the flexible tubing 10. In other examples, the further tubing 52 may be another type of flexible tubing, a non-flexible tubing, or a combination of flexible and non-flexible tubing lengths.

14

The coupling 48 may be any suitable fluid coupling structure, for coupling two tubing ends together, for fluid flow communication. In particular examples, the coupling 48 allows for connection and disconnection of further tubing to the base 42. In the examples of FIGS. 10-14, the coupling 48 may include an in-line tubular structure having a central passage with an inside diameter large enough to receive an end length portion of the third section of the tubing portion 10c. The coupling 48 has an end portion 48a located outside of the base 42, for securing to the further tubing 52. In the example in FIGS. 10-14, further tubing 52 has an inside diameter large enough to receive some or all of the end portion 48a of the coupling 48. In other examples, the end portion 48a of the coupling 48 has an inside diameter large enough to receive an end length portion of the further tubing 52 within the coupling 48. The end length portion of the tubing portion 10c may be fixed and sealed to the coupling 48, and the tubing 52 may be fixed and sealed to the coupling 48 by any suitable mechanism, including friction fitting, adhesives, welds, or the like. In other examples, the coupling 48 may be another suitable in-line coupling device, such as, but not limited to a Luer Lok™ device, Luer™-slip device, slip tip device, hollow needle and septum configuration or the like.

In the example of FIGS. 12 and 13, the coupling 48 or the third section of the tubing (or both) are secured and fixed to the base 42. In further examples, additional structure (not shown) may be included in the base 42, to secure the coupling 48 and the tubing 10 to the base, in a fixed relation. However, the distal length portion 10b of the flexible tubing 10 is sufficiently flexible to flex and bend along the distal length portion 10b. In contexts in which the distal length portion 10b forms a cannula for insertion into a patient's skin, the flexibility of the distal length portion 10b can provide additional comfort to the patient, by allowing the cannula to move and flex with the patient's skin.

As discussed above, the inserter 44 is received and supported by the base 42, but is selectively removable from the base 42. The inserter 44 includes an inserter body 53 and a slotted inserter needle 54. The inserter body 53 may have a handle portion 53a configured to be easily gripped by a human hand. The handle portion 53a may include one or more surfaces with ribs or other contour features, an added friction material, or the like, for enhancing frictional engagement and gripping by a user, tool or machine. In certain examples, the inserter body 53 may include a handle 53a or other portion configured to be gripped or otherwise secured to a separate tool or device, such as an inserter device (not shown) for installing (inserting) the insertion set device 40 in a patient or other entity.

The inserter needle 54 has one end that is fixed in or to the inserter body 53, and extends in the axial dimension direction A of the needle, from the inserter body 53 to an opposite, distal end 54a. The distal end 54a of the inserter needle 54 may have a sharp or tapered shape. The inserter needle 54 has a central channel that is open at the distal end 54a, and a slot-shaped opening 56 into the central channel, extending from the distal end 54a, along at least a portion of its axial length. In some examples, the slot-shaped opening 56 extends the entire length of the inserter needle 54. In other examples, as shown in FIG. 15, the slot-shaped opening extends from the distal end 54a, along a first portion 54b of the length of the inserter needle 54, to a second portion 54c of the length of the inserter needle 54, where the second portion 54c has a fully cylindrical shape (hollow or solid). The inserter needle 54 may correspond to the inserter needle 20 described with reference to FIGS. 6 and 7. In other

15

examples, the inserter needle **54** may have other suitable slotted configurations for functioning in the manner described herein.

In certain examples, the slot-shaped opening **56** has a first segment **56a** with a first slot width, and a second segment **56b** with a second slot width that is larger than the first slot width, as shown in FIG. **15**. A slotted inserter needle **54** having multiple widths such as shown in FIG. **15** can help simplify manufacturing, assembly or set-up procedures, as described below. In certain contexts such simplifying of procedures may help to reduce costs of manufacture and assembly of the insertion set device **40**. In other examples, the slot-shaped opening **56** may have a constant width along its entire length.

The slotted inserter needle **54** may be made of any suitable, rigid material such as, but not limited to, stainless steel or other metal, ceramic, composite material, plastic, or the like. In certain examples, the slotted inserter needle is made of a material that is biologically compatible, for use in contexts in which the inserter needle is to be in contact or connected with a biological entity (such as a human patient or another biological entity). In certain examples, the inserter needle is treated in one or more processes for enhancing biological compatibility or other compatibility for an intended environment or use, such as, but not limited to cleaning, sterilizing, treating or coating with Heparin or other anticoagulant, an antibiotic, nitric-oxide or other materials, or the like.

The slotted inserter needle **54** is configured to receive a portion of the flexible tubing **10** (including the distal end portion **10b** and distal end **10a**) within the central channel of the slotted needle, when the insertion set device **40** is in the first state (as shown in FIGS. **10** and **11**). In that arrangement, the slotted inserter needle **54** is slidable relative to the flexible tubing **10**, in the axial direction A, by moving the inserter **44** in the axial direction, away from the base **42**.

When the insertion set device **40** is in the first state (as shown in FIGS. **10** and **11**), a distal end portion of the slotted inserter needle **54** may be inserted into a patient's skin (or a septum or other structure), a sufficient distance to place the distal end of the flexible tubing **10** in the patient (or through the septum or other structure). The slotted inserter needle **54** provides additional rigidity to the distal end portion **10b** of the flexible tubing **10** during insertion, and can have a pointed or sharp tip to assist in piercing the patient's skin (or septum or other structure) during insertion.

In addition, the surface **46** of the base **42** of the insertion set device **40** may be secured (adhered or otherwise connected) to a surface of the patient's skin (or a septum or other structure), to hold the base **42** onto the patient's skin (or a septum or other structure).

Once the slotted inserter needle **54** containing the distal end portion **10b** of the flexible tubing **10** is inserted into (or partially into) the patient's skin (or a septum or other structure), the slotted inserter needle **54** may be slid off of the flexible tubing **10**, while leaving the distal end **10a** of the flexible tubing **10** in place in the patient (or through the septum or other structure).

In FIG. **12**, the insertion set device **40** is shown in transition between the first state (of FIGS. **10** and **11**) and the second state (of FIG. **13**). In FIG. **12**, the inserter **44** has been moved in the axial direction A from the base **42** a sufficient distance to have caused the slotted inserter needle **54** to have slid partially off of the flexible tubing **10**. In that arrangement, the slotted inserter needle **54** has slid off of the distal end portion **10b** of the flexible tubing **10**.

16

When the insertion set device **40** is in the first state (shown in FIGS. **10** and **11**), and as the slotted inserter needle **54** is being slid off of the distal end portion **10b** of the flexible tubing **10** (shown in FIG. **12**), the second section of the further length portion **10c** of the flexible tubing **10** (forming the bend **10d**) extends out from the slot-shaped opening **56** in the inserter needle **54**. With the flexible tubing **10** extending out of the slot-shaped opening **56**, the slotted inserter needle **54** is allowed to move in the axial direction A relative to the flexible tubing **10** along and past the bend **10d** in the flexible tubing **10**. Accordingly, the slotted inserter needle **54** may slide off of the flexible tubing **10**, while the distal end **10a** of the flexible tubing **10** remains in place in the patient (or through the septum or other structure) and while the other end of the flexible tubing **10** remains connected to the coupling **48**.

Further movement of the inserter **44** in the axial direction A away from the base **42** causes the slotted inserter needle **54** to slide fully off of the flexible tubing **10**. In that arrangement, the insertion set device **40** is in its second state, in which the inserter **44** is fully separated and removed from the base, as shown in FIG. **13**. In the second state, the base **42** may remain secured to the surface of the patient's skin (or a septum or other structure) and the distal end portion **10b** of the flexible tubing **10** forms a cannula through the patient's skin (or a septum or other structure). The inserter **44** may be safely discarded or stored. In other examples, the inserter **44** need not be removed from the base **42** and may be configured to remain coupled to the base **42** (for example, in the position shown in FIG. **12**), as the second state of the insertion set device **40**.

Either before or after securing the base **42** to the patient's skin (or a septum or other structure), or before or after sliding the slotted inserter needle **54** relative to the flexible tubing **10**, the further tubing **52** may be connected in fluid flow communication with the coupling **48**, as described above. Accordingly, the insertion set may be connected to provide a fluid flow connection between the distal end **10a** of the flexible tubing **10** (within a patient, septum or other structure), and a pump or other fluid delivery device or source, sensor, monitor or other device or system connected to the further tubing **52**.

The inserter device **40** may be manufactured and assembled by any suitable manufacturing and assembly processes. An example process **60** in FIG. **16** includes providing a base **42** (at **62**) and providing an inserter **44** (at **64**). The base **42** and the inserter **44** may be made by molding, machining, extruding, stamping or other suitable manufacturing processes. The coupling **48** may be secured to the base **42** and any other components (such as, but not limited to, additional support structure for the tubing **10** or tube-like structure forming the passage **50**) may be formed in or attached to the base **42**. The slotted inserter needle **54** may be formed by molding, machining, extruding, stamping or other suitable manufacturing processes, and may be connected to the inserter body **53** as described above.

The process **60** further includes installing the distal end portion **10b** of the flexible tubing **10** into the slotted inserter needle (at **65**). The distal end portion **10b** of the flexible tubing **10** may be installed in the channel of the slotted inserter needle in any suitable matter, including, but not limited to the matter described with reference to FIG. **15**. As shown in FIG. **15**, the flexible tubing **10** may be assembled with the slotted inserter needle **54** by inserting the tubing **10** into the inserter needle **54**, for example, through the larger width portion **56b** of the slot-shaped opening **56**, and maintaining or pulling a portion of the length of the tubing out of

the larger width portion **56b** of the slot-shaped opening **56**. Then, the portion of the length of the tubing that has been pulled out of the slot-shaped opening **56** may be gripped and forced in the axial direction A, to pull or push the tubing into the smaller slot-width portion **56a** of the inserter needle **54**, until the distal end **10a** of the flexible tubing **10** is positioned within the smaller slot-width portion **56a** of the inserter needle **54** and proximate to the (but not beyond) the distal end **54a** of the needle **54**.

The end of the length of the tubing portion that has been pulled out of the slot-shaped opening (i.e., the opposite end of the flexible tubing **10** relative to the distal end **10a**) is connected to the coupling **48** (at **66**). The tubing end may be connected to the coupling **48** in any suitable manner, including, but not limited to inserting the end portion of the flexible tubing into the coupling **48** and adhering the tubing to the coupling **48** as described above.

Prior to or after coupling the flexible tubing **10** to the coupling **48**, the slotted insertion needle **54** (with the distal end portion **10b** of the tubing) is inserted through the passage **50** (at **68**). In other examples, other suitable manufacturing and assembly processes may be employed to form the insertion set device **40**.

While the size and dimension of the insertion set device **40** and its components may be selected to accommodate the intended application of use, certain sizes and dimensions may be appropriate for certain medical uses. As one example, an insertion set device **40** may include a flexible tubing **10** having a length L of about 6 mm. (or between about 6 mm and about 9 mm). In addition, the flexible tubing **10** may have an outer radius R of about 0.0045 in. (or about 0.1143 mm) and an L/R ratio and R/r ratio as described above in Table 1, to inhibit kinking or buckling along its length dimension. The inserter needle **54** may have a gauge of 27 G, or from 26 G to 30 G, or an outer radius R_N of about 0.0142 in. (or 0.361 mm) or from 0.01 in. to 0.0159 in. (or 0.25 mm to 0.404 mm). The inserter needle **54** may have a first slot width in the smaller width portion **56a** of about 0.007 in. (or 0.18 mm), a second slot width in the larger width portion **56b** of about 0.0095 in. (or 0.24 mm), and a length dimension large enough to receive the full length of the distal end portion **10b** of the tubing, and to extend through the base and either into or through the inserter. In certain examples, when the insertion set device is in the first state (with the distal end portion **10b** of the tubing located within the inserter needle), the minimum distance between the distal end **10a** of the tubing **10** to the start of the needle bevel or taper (of the sharp end of the needle) is about 0.020 inch (or 0.508 mm), to avoid or prevent the distal end **10a** of the tubing **10** from catching on tissue during insertion. The bevel or taper of the sharp end of the inserter needle **54** may have any suitable length along the length dimension of the inserter needle **54**, such as, but not limited to about 0.040 inch (or 1.016 mm), to reduce or minimize patient trauma during insertion. In other examples, the tubing and inserter needle may have other suitable dimensions.

Another example of an insertion set device **70** having a cannula formed with or of a flexible tubing **10** (or other suitable tubing) is described with reference to FIGS. 17-21. The insertion set device **70** is shown in cross-section view in FIG. 17 (corresponding to the cross-section 10-10 in FIG. 11). FIG. 18 shows an enlarged view of a portion of FIG. 17 identified by the circle labeled **18** in FIG. 17.

The insertion set device **70** may be made and may operate and function as described above with respect to the insertion set device **40**, with certain differences discussed below. The insertion set device **70** has a base **72** and an inserter **74**,

which may correspond in structure and function to the base **42** and inserter **44**, respectively, as discussed above, with certain differences discussed below.

The inserter **74** has a slotted inserter needle **75**, which may correspond to the slotted inserter needle **54** described above. However, the slotted inserter needle **75** may include a slot having a constant width along its length (and need not include two different slot widths, as described with respect to the slotted inserter needle **54** shown in FIG. 15). The slotted inserter needle **75** has a distal end **75a** corresponding to the distal end **54a** of the slotted inserter needle **54**.

In the insertion set device **70**, the flexible tubing **10** includes a distal end **10a** and distal end portion **10b**, as discussed above. The distal end **10a** and a distal length portion **10b** of the tubing **10** extends out from a first opening **72a** in a surface **76** of the base **72**. The first opening **72a** and surface **76** may correspond to the first opening **42a** and surface **46** of the insertion set device **40** discussed above.

A further length portion **10c** of the tubing **10** is located within the base **72** and extends from the distal length portion **10b**, to a chamber **78** within the base **72**. The further length portion **10c** of the tubing **10** has an end (opposite to the distal end **10a**) that is open to and in fluid flow communication with the chamber **78**. The chamber **78** is located in axial alignment with the tubing **10** and the slotted inserter needle **75**. Accordingly, the entire length of the tubing **10** in the insertion set device **70** may be normally straight (and need not include a bend **10d** as in the inserter set device **40**). However, the distal end portion **10b** of the tubing **10** may be flexible when the inserter needle **75** is withdrawn.

The chamber **78** may be a sealed interior volume within the base **72**, through which fluid may flow and change flow direction, as described herein. The chamber **78** may be formed directly within the material of the base **72**. In other examples, the chamber **78** may be the interior of a container structure located and fixed within the base **72**.

The base **72** has a first needle passage **80** (corresponding to the passage **50** in the insertion set device **40**), that extends, linearly, from the opening **72a** to the chamber **78**. The base **72** also includes a first septum **82**, located between the chamber **78** and a second opening **72b** in the base **72**. The second opening **72b** may correspond to the second opening **42b** in the insertion set device **40**. The first septum **82** is made of a material suitable to be pierced through by the slotted inserter needle **75**, and may be a self-sealing septum material, such as, but not limited to silicon, other rubber material, or the like.

When the insertion set device **70** is in a first state, as shown in FIG. 17, the slotted inserter needle **75** is extended through the first septum **82**, the chamber **78** and the needle passage **80**. In addition, when the insertion set device **70** is in a first state, as shown in FIG. 17, the flexible tubing **10** (including the distal end **10a**) is located within the central channel of the slotted inserter needle **75**, and a distal end **75a** of the slotted inserter needle **75** is located beyond the distal end **10a** of the flexible tubing **10**.

The base **72** includes a second needle passage **84** extending linearly and transverse to the axial dimension A and, thus, transverse to the direction of first needle passage **80** and the flexible tubing **10**. In certain examples, the second needle passage **84** extends perpendicular to the axial dimension A. In other examples, the second needle passage **84** extends at an angle between about 90° and about 160° (or, in particular examples, between about 135° and about 160° relative to the axial dimension A. The second needle passage **84** may be formed directly within the material of the base **72** (such as, by boring, molding or otherwise forming a channel

19

through the material of the base). In other examples, the second needle passage **84** may be the interior of a tube structure included in and fixed to the base **72**. The second needle passage **84** has an open end **84a**, opening to the exterior of the base **72**.

A second septum **86** is located in the second needle passage **84**, or between the second needle passage **84** and the chamber **78**. The second septum **86** is made of a material suitable to be pierced through by a further needle **88**, and may be a self-sealing septum material, such as, but not limited to materials as described above with respect to the first septum **82**. The further needle **88** may be a hollow needle for coupling a further tubing **90** in fluid flow communication with the chamber **78** in the base **72**. The further tubing **90** may correspond to the further tubing **52** connected to the insertion set device **40**, and may connect the insertion set device **70** to other devices and systems as described herein with respect to the further tubing **52**.

As shown in FIG. **17**, the further needle **88** extends through the second needle passage **84** and through the second septum **86**. The further needle **88** has a first end (such as a sharp or pointed end) **88a**, located within the chamber **78**, and a second end **88b**, located in the further tubing **90**. The further tubing **90** may be coupled and sealed to the further tubing **90**, and has a central passage providing a fluid flow path between the further tubing **90** and the chamber **78** in the base **72**.

In particular examples, the further needle **88** and the second septum **86** provide a connector structure that allows the further tubing **90** to be selectively connected or disconnected from the base **72**. For example, the further needle **88** may be moved from a position in which the distal end **88a** of the further needle **88** is fully outside of the second needle passage **84**, to a connected position shown in FIG. **17**, by moving the needle **88** through the second needle passage **84** in the direction of arrow **92**, until the distal end **88a** of the needle **88** pierces through the second septum **86** and is located within the chamber **78**. From that position, the further needle **88** may be withdrawn from the second septum **86** and from the base **72**, by moving the needle **88** along the second needle passage **84**, in a direction opposite to the direction of arrow **92**, to selectively disconnect the further tubing **90** from the chamber **78** and from the base **72**. Other examples may have other suitable coupling structures for coupling the further tubing **90** to the chamber **78** and the base **72**, including but not limited to the coupling devices described above with respect to coupling **48**.

In the insertion set device **70**, one or more additional features may be provided to hold the flexible tubing **10** within the first needle passage **80**, in a fixed relation to the base **72**. In certain examples, a collar structure **92** may be provided within the first needle passage **80**, to hold the flexible tubing **10** in a fixed relation to the base **72**. The collar structure **92** may be adhered to the flexible tubing **10** and to the base **72** by any suitable mechanism, including but not limited to friction fitting, adhesives, welds, or the like.

The collar structure **92** may be made of a material suitable to be pierced through by the slotted inserter needle **75**, and may be a self-sealing septum material, such as, but not limited to materials as described above with respect to the first septum **82**. When the insertion set device **70** is in the first state shown in FIG. **17**, the slotted inserter needle **75** is pierced through the collar structure **92** and contains the flexible tubing **10** within its central channel, as shown in the cross-section drawing of FIG. **19** (taken perpendicular to the axial dimension A, within the base **72**, below the chamber **78**). In certain examples, the collar structure **92** may extend

20

around some, but not the entire circumference of the tubing **10**, without covering a surface portion **10e** of the tubing **10** that is exposed through the slot shaped opening of the inserter needle **75**, as shown in FIG. **19**. In certain examples, additional adhesive material, welding or the like may be provided along the surface **10e** of the flexible tubing **10**, to adhere the surface **10e** of the tubing **10** to the base **72**. The collar structure **92** or the additional adhesive or welding retains and holds the flexible tubing **10** to the base **72**, as and after the slotted inserter needle **75** is withdrawn and slid off of the flexible tubing **10**. In other examples, other suitable structure may be provided for fixing the flexible tubing **10** to the base **72**.

The insertion set device **70** is shown in FIGS. **20** and **21**, in a second state, in which the inserter **74** (including the slotted inserter needle **75**) has been fully withdrawn from the base **72**. The drawing in FIG. **21** shows the cross-section view of FIG. **19**, but with the slotted inserter needle **75** removed from the collar structure **92**, where the collar structure **92** is made of a self-sealing material that has sealed after removal of the needle **75**.

Another example of an insertion set device **100** having a cannula formed with or of a flexible tubing **10** (or other suitable tubing) is described with reference to FIGS. **22-25**. In FIGS. **23** and **25**, the insertion set device **100** is shown in cross-section views (corresponding to the cross-section **10-10** in FIG. **11**), in the first state and the second state, respectively. FIG. **23** shows an enlarged view of a portion of FIG. **22** identified by the circle labeled **23**, and FIG. **24** shows a further enlarged view of features of the insertion set device **100**.

The insertion set device **100** may be made and may operate and function as described above with respect to the insertion set devices **40** and **70**, with certain differences discussed below. The insertion set device **100** has a base **102** and an inserter **104**, which may correspond in structure and function to the base **42** (or base **72**) and inserter **44** (or inserter **74**), respectively, as discussed above, with certain differences discussed below. The base **102** includes a needle passage **103** (corresponding to the needle passage **50** in the insertion set device **40**).

The inserter **104** has a slotted inserter needle **105**, which may correspond to the slotted inserter needle **54** (or **75**) described above. However, the slotted inserter needle **105** may include a slot having a constant width along its length (and need not include two different slot widths, as described with respect to the slotted inserter needle **54** shown in FIG. **15**). The slotted inserter needle **105** has a distal end **105a** corresponding to the distal end **54a** (or **75a**) of the slotted inserter needle **54** (or **75**).

In the insertion set device **100**, the flexible tubing **10** includes a distal end **10a** and distal end portion **10b**, as discussed above. The distal end **10a** and a distal length portion **10b** of the tubing **10** extends out from a first opening **102a** in a surface **106** of the base **102**. The first opening **102a** and surface **106** may correspond to the first opening **42a** and the surface **46** of the insertion set device **40** discussed above (or the first opening **72a** and the surface **76** of the insertion set device **70** discussed above).

A further length portion **10c** of the tubing **10** is located within the needle passage **103** in the base **102** and extends from the distal length portion **10b**, to a holding pin that may be a rigid wire or stop structure **108** within the base **102**. The further length portion **10c** of the tubing **10** has an end (opposite to the distal end **10a**) that is abutted against the rigid wire or stop structure **108**. In the example of FIG. **23**, the rigid wire or stop structure **108** has an elongated wire or

21

shaft shape with a distal end portion **108a** and a bent portion **108b** adjacent the distal end portion **108a**. The distal end portion **108a** may extend partially into the second end of the tubing **10** opposite to the distal end **10a**. Alternatively, the distal end portion **108a** may contact the end of the tubing **10**, without extending into the tubing **10**.

The rigid wire or stop structure **108** has a length section that extends within the base **102**, and is fixed to the base **102**. The rigid wire or stop structure **108** may be molded into the base, or may be fixed to the base **102** by any other suitable mechanism, including but not limited to friction fitting, adhesives, welds, or the like. The rigid wire or stop structure **108** holds and retains the flexible tubing **10** in the base and keeps the flexible tubing **10** from moving with the slotted inserter needle **105**, as the slotted inserter needle **105** is withdrawn from the base **102**. The bent portion **108b** of the rigid wire or stop structure **108** extends out from the slot-shaped opening in the slotted inserter needle **105**, when the insertion set device **100** is in the first state shown in FIG. **22**, and as the slotted inserter needle **105** is being withdrawn from the base **102**.

The base **102** includes a hollow tube structure **110** having a first end **110a** connected in fluid flow communication with the further length portion **10c** of the tubing **10**. In one example, the end **110a** of the tube structure **110** is inserted partially into the side of the further length portion **10c** of the flexible tubing **10**. The tube structure **110** extends through the slot-shaped opening in the slotted inserter needle **105**, when the insertion set device **100** is in the first state shown in FIG. **22**, and as the slotted inserter needle **105** is being withdrawn from the base **102**. The tube structure **110** provides a fluid flow passage to or from the flexible tubing **10**. In certain examples, the tube structure **110** may have an oval or widened cross-section shape (as shown in the further view of FIG. **24**), to provide a greater fluid flow volume, relative to a tube structure having a round cross-section that would fit through the slot-shaped opening in the slotted inserter needle **105**.

The hollow tube structure **110** may have a second end **110b** connected in fluid flow communication with a coupling **112**. The coupling **112** may correspond to the coupling **48** of the insertion set device **40**, or another suitable fluid coupling device, for coupling a further tubing **114** to the base **102**, in fluid flow communication with the tube structure **110**. The further tubing **114** may correspond to the further tubing **52** or the further tubing **90** discussed above.

The hollow tube structure **110** extends from the further length portion **10c** of the tubing **10** to the coupling **112**. The length dimension of the hollow tube structure **110** may extend linearly and transverse to axial dimension **A** of the tubing **10**, such that the height **H** in the axial dimension of the base **102** (dimension between the surface **106** and the opposite facing surface) may be made relatively small or minimized. In certain examples, the hollow tube structure **110** extends at about 90° relative to the axial dimension, such that the coupling **112** is directed about 90° from the direction of distal length portion **10b** of the tubing **10**. This arrangement allows the further tubing **114** to be connected to the coupling **112**, external to the base **102**, and extend outward from the base **102**, substantially parallel to and along the surface of the patient's skin (or other surface) to which the base **102** secures. Accordingly, the base **102** and tubing **10** may be more easily concealed under clothing or the like. In other examples, the hollow tube structure **110** may extend at an angle between about 90° and about 160° (or, in particular examples, between about 135° and about 160°), relative to the axial dimension **A**.

22

Another example of an insertion set device **120** having a cannula formed with or of a flexible tubing **10** (or other suitable tubing) is described with reference to FIGS. **26-29**. In FIGS. **26** and **29**, the insertion set device **120** is shown in cross-section views (corresponding to the cross-section **10-10** in FIG. **11**), in the first state and the second state, respectively. FIG. **27** shows an enlarged view of a portion of FIG. **26** identified by the circle labeled **27** in FIG. **26**, and FIG. **28** shows a further enlarged view of features of the insertion set device **120**.

The insertion set device **120** may be made and may operate and function as described above with respect to the insertion set device **100**, with certain differences discussed below. The insertion set device **120** has a base **122** and an inserter **124**, which may correspond in structure and function to the base **102** (or bases **42** or **72**) and inserter **104** (or inserters **44** or **74**), respectively, as discussed above, with certain differences discussed below. The base **122** includes a needle passage **123** (corresponding to the needle passage **103** in the insertion set device **100**).

The inserter **124** has a slotted inserter needle **125**, which may correspond to the slotted inserter needle **105** (or **54** or **75**) described above. The slotted inserter needle **125** may include a slot having a constant width along its length (and need not include two different slot widths, as described with respect to the slotted inserter needle **54** shown in FIG. **15**). The slotted inserter needle **125** has a distal end **125a** corresponding to the distal end **105a** (or **54a** or **75a**) of the slotted inserter needle **105** (or **54** or **75**).

In the insertion set device **120**, the flexible tubing **10** includes a distal end **10a** and distal end portion **10b**, as discussed above. The distal end **10a** and a distal length portion **10b** of the tubing **10** extends out from a first opening **122a** in a surface **126** of the base **122**. The first opening **122a** and surface **126** may correspond to the first opening **102a** and the surface **126** of the insertion set device **100**.

A further length portion **10c** of the tubing **10** is located within the needle passage **123** in the base **122** and extends from the distal length portion **10b**, to a rigid, hollow tube **128** within the base **122**. The further length portion **10c** of the tubing **10** has an end (opposite to the distal end **10a**) that is abutted against the rigid tube **128**. In the example of FIG. **26**, the rigid tube **128** has an elongated tubular shape with a distal end portion **128a** and a bent portion **128b** adjacent the distal end portion **128a**. The distal end portion **128a** may extend partially into the second end of the tubing **10** opposite to the distal end **10a**. Alternatively, the distal end portion **128a** may connect to the end of the tubing **10** through a fluid flow connector, without extending into the tubing **10**.

The hollow, rigid tube **128** has a length section that extends within the base **122** (between the bent portion **128b** and a second end **128c**), and is fixed to the base **122**. The rigid tube **128** may be molded into the base **122**, or may be fixed to the base **122** by any other suitable mechanism, including but not limited to friction fitting, adhesives, welds, or the like. The rigid tube **128** holds and retains the flexible tubing **10** in the base and keeps the flexible tubing **10** from moving with the slotted inserter needle **125**, as the slotted inserter needle **125** is withdrawn from the base **122**. The bent portion **128b** of the rigid tube **128** extends out from the slot-shaped opening in the slotted inserter needle **125**, when the insertion set device **120** is in the first state shown in FIG. **26**, and as the slotted inserter needle **125** is being withdrawn from the base **122**.

The hollow, rigid tube **128** has a fluid flow channel that provides a fluid flow path between the tubing **10** and a further tubing **130**. The further tubing **130** may correspond

to the further tubing **114**, **90** or **52** discussed above. The further tubing **130** may be connected in fluid flow communication with a second end **128c** of the hollow, rigid tube **128** (opposite to the distal end portion **128a**) within the base **122** (as shown in FIGS. **26** and **29**), or outside of the base **122**. For example, a portion of the hollow, rigid tube **128** and the second end **128c** may extend into the further tubing **130** and be sealed and adhered to the further tubing **130** by any suitable mechanism, including, but not limited to adhesives, welding or the like. Alternatively, the hollow, rigid tube **128** may be connected in fluid flow communication with the further tubing through any suitable in-line or other fluid flow coupling device, such as, but not limited to a Luer Lok™ device, Luer™-slip device, slip tip device, hollow needle and septum configuration or the like.

The hollow, rigid tube **128** may have a round cross-section shape (taken perpendicular to its length dimension), and may be made of any suitable, rigid material such as, but not limited to stainless steel or other metal, plastic, ceramic, composite material, or the like. The hollow, rigid tube **128** may be made by any suitable manufacturing process including, but not limited to molding, machining, extruding, stamping or other the like.

The hollow, rigid tube **128** has a length section **128d** that extends within the base **122** between the bent portion **128b** and a second end **128c**. Due to the bent portion **128b**, the length section **128d** of the hollow, rigid tube **128** may extend linearly and transverse to axial dimension A of the tubing **10**, such that the height H in the axial dimension of the base **122** (dimension between the surface **106** and the opposite facing surface) may be made relatively small or minimized. In certain examples, the length section **128d** of the hollow, rigid tube **128** extends at about 90° relative to the axial dimension. This arrangement allows the further tubing **130** to be connected and extend outward from the base **122**, substantially parallel to and along the surface of the patient's skin (or other surface) to which the base **122** secures. Accordingly, the base **122** and tubing **10** may be more easily concealed under clothing or the like. In other examples, the length section **128d** of the hollow, rigid tube **128** may extend at an angle between about 90° and about 160° (or, in particular examples, between about 135° and about 160°), relative to the axial dimension A.

Another example of an insertion set device **140** having a cannula formed with or of a flexible tubing **10** (or other suitable tubing) is described with reference to FIGS. **30-32**. In FIG. **30**, the insertion set device **140** is shown in a cross-section view (corresponding to the cross-section **10-10** in FIG. **11**), in the first state. FIG. **31** shows an enlarged view of a portion of FIG. **30** identified by the circle labeled **31**, and FIG. **32** shows a further enlarged view of features of the insertion set device **140**.

The insertion set device **140** may be made and may operate and function as described above with respect to the insertion set device **70**, with certain differences discussed below. The insertion set device **140** has a base **142** and an inserter **144**, which may correspond in structure and function to the base **72** and inserter **74**, respectively, as discussed above, with certain differences discussed below. The base **142** includes a needle passage **143** (corresponding to the needle passage **80** in the insertion set device **70**).

In the insertion set device **140**, the flexible tubing **10** includes a distal end **10a** and distal end portion **10b**, as discussed above. The distal end **10a** and a distal length portion **10b** of the tubing **10** extends out from a first opening **142a** in a surface **146** of the base **142**. The first opening **142a** and surface **146** may correspond to the first opening **72a** and

the surface **76** of the insertion set device **70**. A further length portion **10c** of the tubing **10** is located within the needle passage **143** in the base **142** and extends from the distal length portion **10b**, to a chamber **148** (corresponding to the chamber **78** in the insertion set device **70**). The insertion set device **140** also includes a first septum **152**, a second needle passage **154** and a second septum **156** (corresponding to the first septum **82**, the second needle passage **84** and the second septum **86** in the insertion set device **70**). In addition, the insertion set device **140** may be configured to connect with a further needle **88** and a further tubing **90**, as discussed above with respect to the insertion set device **70**.

The inserter **144** has a hollow inserter needle **145** that has a central channel extending along its entire length. In some examples, the inserter needle **145** may correspond to the slotted inserter needle **75** described above. However, in other examples, the inserter needle **145** need not be slotted and, instead, may have a hollow, fully round cylindrical configuration. In addition, the inserter needle **145** is configured to be received by and selectively removable from a body portion **147** of the inserter **144**. The body portion **147** of the inserter **144** may correspond to the body portion of the inserter **74** (and the inserter body **53**) described above, but includes a needle passage **150** extending linearly through the body portion **147**. The needle passage **150** is arranged to be in linear alignment with the needle passage **143** in the base **142** and is coaxial with the axis A of the tubing **10**, when the insertion set device **140** is in the first state as shown in FIG. **30**.

The insertion set device **140** also includes a removable holding pin **160** having a first end **160a** and an opposite second end **160b**. When the insertion set device **140** is in the first state (as shown in FIGS. **30** and **31**), the holding pin **160** is received within, and extends along a portion of the length of the hollow inserter needle **145**, but is removable from the hollow inserter needle **145** by sliding out of the channel of the needle **145**, along a direction of the axis A.

In that first state, the tubing **10** is also received with and extends along another portion of the length of the hollow inserter needle **145**. The holding first end **160a** of the holding pin **160** is arranged to abut the second end of the tubing **10** (opposite to the distal end **10a**), within the channel of the hollow inserter needle **145**, while the second end **160b** of the holding pin **160** is exposed (for example, by extending out from an opening **147a** in the inserter body portion **147**) at an end of the needle passage **150**. In certain examples, the holding pin **160** may extend partially into the second end of the tubing **10**. In other examples, the holding pin **160** contacts, but does not enter the tubing **10**. The opening **147a** in the inserter body portion **147** may be flared so as to taper wider from the width of the needle passage **150** to a wider width at the open end of the opening **147a**, for easier access to the hollow inserter needle **145**.

The insertion set device **140** may include a collar structure **162** within the needle passage **143** and around the length portion **10c** of the tubing **10**, to help retain the tubing **10** within and fixed to the base **142**, when the inserter needle **145** and the holding pin **160** are removed. The collar structure **162** may be made of a material suitable to be pierced through by the hollow inserter needle **145**, and may be a self-sealing septum material, such as, but not limited to materials as described above with respect to the collar structure **92** described above. The collar structure **162** may be adhered to the flexible tubing **10** and to the base **142** by any suitable mechanism, including but not limited to friction fitting, adhesives, welds, or the like.

25

When the insertion set device **140** is arranged in the first state (as shown in FIGS. **30** and **31**), the entire length of the tubing **10** and a portion of the length of the holding pin **160** are received within the channel of the hollow inserter needle **145**. In addition, the holding pin **160** abuts the tubing **10**, to retain and hold the tubing **10** from moving with the hollow inserter needle **145**, when the hollow inserter needle **145** is being withdrawn.

In that first state, the insertion set device **140** may be inserted or installed on a patient, septum or other device, and the further tubing **90** may be connected to the base **142** (similar to the manner of installing devices in examples of FIGS. **10-29**, as described above)

After insertion or installation of the insertion set device **140**, the hollow inserter needle **145** is withdrawn from the base **142** and inserter **144**, by moving the hollow needle in the direction of the axis A, away from the inserter **144**. For example, a user (or tool or machine) may grip the hollow inserter needle **145** near the end **145b**, and may pull the hollow inserter needle **145** outward (upward in FIG. **30**) along the direction of the axis A of the needle passages **143** and **150** and of the tubing **10**, to withdraw the hollow needle from the base **142** and the inserter **144**. At the same time, the holding pin **160** remains abutted with the tubing **10**, to retain the tubing **10** within the base **142**, and keep the tubing **10** from moving with the hollow inserter needle **145**, as the inserter needle is withdrawn.

Once the hollow inserter needle **145** has been fully withdrawn, the holding pin **160** may be withdrawn by moving the holding pin **160** in the direction of the axis A, away from the inserter **144**. For example, a user (or tool or machine) may grip the holding pin **160**, near the exposed second end **160b**, and may pull the holding pin **160** outward (upward in FIG. **30**) along the direction of the axis A of the needle passage **150**, away from the tubing **10**, to withdraw the holding pin **160** from the base **142** and the inserter **144**. At the same time, the tubing **10** remains retained within and fixed to the base **142**, by the collar structure **162**. Accordingly, the insertion set device **140** is transitioned to the second state (as shown in FIG. **32**), after the inserter needle **145** and the holding pin **160** have been withdrawn.

While various exemplary embodiments have been presented in the foregoing detailed description, it should be appreciated that a vast number of variations exist. It should also be appreciated that the exemplary embodiment or embodiments described herein are not intended to limit the scope, applicability, or configuration of the claimed subject matter in any way. Rather, the foregoing detailed description will provide those skilled in the art with a convenient road map for implementing the described embodiment or embodiments. It should be understood that various changes can be made in the function and arrangement of elements without departing from the scope defined by the claims, which includes known equivalents and foreseeable equivalents at the time of filing this patent application.

We claim:

1. An insertion set system comprising:

a base configured to be secured externally to a patient;
a flexible tubing supported by the base and having a distal end portion located external to the base, the distal end portion forming a cannula that is configured to be inserted into the patient, when or while the base is secured externally to the patient; and

an inserter having a needle, the needle having a needle channel within the needle in which at least the distal end portion of the flexible tubing is received such that the distal end portion of the flexible tubing is located

26

within the needle, the needle being able to slide relative to the flexible tubing, to selectively withdraw the needle off of at least the distal end portion of the flexible tubing.

2. The insertion set system of claim **1**, wherein the needle and the flexible tubing are in a first state in which at least the distal end portion of the flexible tubing is received in the needle channel, and wherein the needle is moveable along a length dimension of the distal end portion of the flexible tubing to a second state in which the needle is separated from the distal end portion of the flexible tubing.

3. The insertion set system of claim **1**, further comprising a fluid coupling, wherein the flexible tubing has a second end opposite the distal end portion, and wherein the second end of the flexible tubing is connected in fluid flow communication with the fluid coupling.

4. The insertion set system of claim **3**, wherein:

the needle of the inserter having a length dimension and a slot-shaped opening extending along at least a portion of the length dimension, the slot-shaped opening being open to the needle channel;

the flexible tubing includes a length portion extending from the distal end portion to the second end of the flexible tubing, the length portion extending out of the needle channel, through the slot-shaped opening of the needle.

5. The insertion set system of claim **4**, wherein the length portion of the flexible tubing that extends out of the needle channel has a bend of between 90° and 160° .

6. The insertion set system of claim **4**, wherein the slot shaped opening in the needle has a first width extending from a distal end of the needle, along a first portion of the length dimension of the needle, and a second width extending along a second portion of the length dimension of the needle, the second width being larger than the first width.

7. The insertion set system of claim **1**, wherein:

the distal end portion of the flexible tubing has a length extending along an axial dimension of the flexible tubing;

the base has a chamber in fluid flow communication with the flexible tubing; and

the base has a fluid flow channel extending transverse to the axial dimension.

8. The insertion set system of claim **7**, wherein the channel in the base extends from the chamber at an angle of between 90° and 160° relative to an axial dimension of the distal end portion of the flexible tubing.

9. The insertion set system of claim **7**, further comprising a first septum on the base, at a location in alignment with the axial dimension of the flexible tubing and the chamber, wherein the needle extends through the first septum and the chamber, when the distal end portion of the flexible tubing is received in the needle channel.

10. The insertion set system of claim **9**, further comprising a second septum located in the channel of the base or between the channel of the base and the chamber, the second septum configured to be pierced by a further needle for connection of a further tubing to the channel of the base.

11. The insertion set system of claim **7**, wherein:

the flexible tubing has a further length portion extending from the distal end portion into the base;

the base includes a tubing channel through which the further length portion of the flexible tubing extends, and a collar fixing the further length portion of the flexible tubing to the base within the needle channel of the base, wherein the needle is pierced through the

collar when the distal end portion of the flexible tubing is received in the needle channel.

12. The insertion set system of claim 7, wherein: the flexible tubing has a further length portion extending from the distal end portion into the base;

the insertion set system further comprising a holding pin arranged and configured to abut an end portion of the further length portion of the flexible tubing and inhibit movement of the flexible tubing with the needle while the needle is being withdrawn off of the distal end portion of the flexible tubing, the holding pin being moveable away from the end portion of the further length of the flexible tubing, after the needle has been withdrawn off of the distal end portion of the flexible tubing.

13. The insertion set system of claim 1, wherein: the distal end portion of the flexible tubing has a length extending along an axial dimension of the flexible tubing;

the flexible tubing has a further length portion extending from the distal end portion into the base; and the insertion set system further comprising a holding pin arranged and configured to abut an end portion of the further length portion of the flexible tubing and inhibit movement of the flexible tubing with the needle while the needle is being withdrawn off of the distal end portion of the flexible tubing.

14. The insertion set system of claim 13, wherein the holding pin comprises a rigid wire or stop structure that is fixed to the base.

15. The insertion set system of claim 13, wherein: the needle of the inserter has a length dimension and a slot-shaped opening extending along at least a portion of the length dimension, the slot-shaped opening being open to the needle channel; and the holding pin extends out of the needle channel, through the slot-shaped opening of the needle.

16. The insertion set system of claim 1, wherein: the flexible tubing has a further length portion extending from the distal end portion into the base; the insertion set system further comprising a rigid hollow tube connected in fluid flow communication with an end portion of the further length portion of the flexible tubing and abutting the end portion of the further length portion of the flexible tubing to inhibit movement of the flexible tubing with the needle while the needle is being withdrawn off of the distal end portion of the flexible tubing.

17. The insertion set system of claim 16, wherein: the needle of the inserter has a length dimension and a slot-shaped opening extending along at least a portion of the length dimension, the slot-shaped opening being open to the needle channel; and the rigid hollow tube has a length portion that extends out of the needle channel, through the slot-shaped opening of the needle.

18. The insertion set system of claim 16, wherein the rigid hollow tube is fixed to the base and is configured to be

connected in fluid flow communication with a further tubing located at least partially external to the base.

19. The insertion set of claim 1, wherein the needle comprises a structure made of a material having sufficient rigidity to pierce skin of the patient, the needle structure having a hollow interior that defines the channel within the needle and in which the distal end portion of the flexible tubing is located.

20. The insertion set of claim 1, wherein the base has a surface that is configured to be secured to the patient, external to the patient's skin.

21. The insertion set of claim 1, wherein the base has a surface on which an adhesive is provided, for securing the base to a patient's skin.

22. The insertion set of claim 1, wherein the needle extends through the base when the distal end portion of the flexible tubing is located within the needle.

23. An insertion set system, comprising: a base configured to be secured to a patient; a flexible tubing supported by the base and having a distal end portion located external to the base, the distal end portion forming a cannula that is configured to be inserted into the patient, when or while the base is secured to the patient; and

an inserter having a needle, the needle having a needle channel in which at least the distal end portion of the flexible tubing is received, the needle being able to slide relative to the flexible tubing, to selectively withdraw the needle off of at least the distal end portion of the flexible tubing;

wherein: the flexible tubing has a further length portion extending from the distal end portion into the base; and the base includes a tubing channel through which the further length portion of the flexible tubing extends, and a collar fixing the further length portion of the flexible tubing to the base within the needle channel of the base, wherein the needle is pierced through the collar when the distal end portion of the flexible tubing is received in the needle channel.

24. A method of making an insertion set system comprising:

- providing a base configured to be secured externally to a patient;
- supporting a flexible tubing supported by the base, with a distal end portion of the flexible tubing located external to the base, the distal end portion forming a cannula that is configured to be inserted into the patient, when or while the base is secured to the patient;
- receiving by the base, an inserter having a needle, the needle having a needle channel within the needle;
- receiving at least the distal end portion of the flexible tubing in the needle channel within the needle for sliding movement, wherein the needle is able to slide relative to the flexible tubing, to selectively withdraw the needle off of at least the distal end portion of the flexible tubing.

* * * * *